By Mrs. KELLY (for herself and Ms. MILLENDER-MCDONALD):

H. Res. 313. Resolution expressing the sense of the House of Representatives regarding Government procurement access for women-owned businesses; to the Committee on Government Reform and Oversight.

By Mr. GEPHARDT:

H. Res. 315. Resolution relating to a question of the privileges of the House; considered and laid on the table.

By Ms. SANCHEZ:

H. Res. 316. Resolution recognizing and honoring former South Vietnamese commandos for their heroism, sacrifice, and service during the Vietnam conflict; to the Committee on International Relations.

¶129.28 PRIVATE BILLS AND RESOLUTIONS

Under clause 1 of rule XXII.

Mr. ROTHMAN introduced a bill (H.R. 2976) for the relief of Alexandre Malofienko, Olga Matsko, and their son, Vladimir Malofienko; which was referred to the Committee on the Judiciary.

¶129.29 ADDITIONAL SPONSORS

Under clause 4 of rule XXII, sponsors were added to public bills and resolutions as follows:

H.R. 68: Mr. BONIOR, Mr. COYNE, Mr. CUMMINGS, Ms. DANNER, Mr. FARR of California, Mr. FILNER, Mr. HASTINGS of Florida, Mr. MCINTYRE, Mr. SANDERS, Mr. TOWNS, Mr. UNDERWOOD, and Mr. VENTO.

H.R. 104: Mr. RADANOVICH.

H.R. 107: Mr. PAYNE.

H.R. 135: Mr. CUNNINGHAM, Mr. BOEHLERT, and Mrs. EMERSON.

H.R. 164: Mr. JOHNSON of Wisconsin, Mr. SANDLIN, Mr. KENNEDY of Massachusetts, and Mr. PRICE of North Carolina.

H.R. 306: Mr. HALL of Ohio and Mr. RANGEL.

H.R. 519: Mr. FARR of California.

H.R. 611: Ms. KILPATRICK.

H.R. 725: Mr. FAZIO of California.

H.R. 806: Ms. FURSE.

H.R. 902: Mr. GINGRICH, Mr. BURR of North Carolina, Mr. FRANKS of New Jersey, Mr. SALMON, Mr. UPTON, and Mr. WHITFIELD.

H.R. 1023: Mr. HOUGHTON.

H.R. 1038: Mr. FRANK of Massachusetts.

H.R. 1043: Mr. SHERMAN.

H.R. 1054: Mr. MCCRERY, Mr. MCGOVERN, and Mr. NEAL of Massachusetts.

H.R. 1070: Ms. MILLENDER-MCDONALD.

H.R. 1126: Mr. JOHNSON of Wisconsin.

H.R. 1165: Mr. JOHNSON of Wisconsin.

H.R. 1241: Mr. WATTS of Oklahoma.

H.R. 1319: Mr. SALMON.

H.R. 1322: Mr. PACKARD.

H.R. 1354: Mr. LATOURETTE.

H.R. 1362: Mr. DEUTSCH.

H.R. 1375: Ms. BROWN of Florida and Mr. DAVIS of Virginia.

H.R. 1382: Mr. FATTAH and Mr. KUCINICH.

H.R. 1453: Ms. FURSE.

H.R. 1521: Mr. RADANOVICH.

H.R. 1614: Mr. COYNE.

H.R. 1625: Mr. MCINNIS and Mr. BRYANT.

H.R. 1631: Ms. STABENOW.

H.R. 1689: Mr. SALMON and Mr. NEAL of Massachusetts.

H.R. 1891: Mrs. EMERSON, Mr. HAYWORTH, Mr. CRANE, Mr. UPTON, Mr. CAMP, and Mr. NEAL of Massachusetts.

H.R. 1995: Ms. RIVERS, Mr. KILDEE, Mr. EVANS, Ms. WATERS, Mr. DELAHUNT, Mr. HEFNER, Mr. BONIOR, Mr. SERRANO, Mr. CARDIN, Mrs. MORELLA, Ms. HARMAN, Mr. LEWIS of Georgia, Mrs. KENNELLY of Connecticut, Mr. SANDERS, Mr. MURTHA, Mr. POMEROY, Mr. OWENS, Mr. ABERCROMBIE, Ms. VELAZQUEZ, Mr. BROWN of Ohio, and Mr. MOAKLEY.

H.R. 2023: Mr. KUCINICH.

H.R. 2029: Mr. SCARBOROUGH.

H.R. 2139: Mr. STRICKLAND, Ms. WOOLSEY, and Mr. COOK.

H.R. 2183: Mr. EWING.

H.R. 2186: Mr. HANSEN, Ms. LOFGREN, Mr. PACKARD, and Mr. COOK.

H.R. 2202: Mr. JOHNSON of Wisconsin.

H.R. 2275: Mr. FROST, Mr. FILNER, Mr. MCHUGH, Mr. EVANS, Mrs. KELLY, Mrs. MINK of Hawaii, Mr. ACKERMAN, Mr. SANDLIN, Mrs. TAUSCHER, and Ms. DELAURO.

H.R. 2305: Mr. PORTMAN.

H.R. 2348: Mr. STARK, Mr. ROYCE, Mr. PACKARD, Mr. RADANOVICH, Mr. CAMPBELL, Mr. BILBRAY, Mr. HUNTER, Mr. POMBO, Mr. KIM, Mr. MCKEON, Mrs. TAUSCHER, Mr. BONO, Mr. CUNNINGHAM, Ms. SANCHEZ, Mr. HERGER, Mr. DOOLITTLE, Ms. ESHOO, Mr. THOMAS, Mr. BECERRA, Mr. CALVERT, Mr. HORN, Mr. LANTOS, Mr. ROHRABACHER, Mr. BROWN of California, and Mr. GALLEGLY.

H.R. 2349: Mr. HERGER, Mr. DOOLITTLE, Ms. ESHOO, Mr. THOMAS, Mr. BECERRA, and Mr. CALVERT.

H.R. 2356: Mr. DREIER.

H.R. 2391: Mr. RAHALL.

H.R. 2396: Ms. LOFGREN, Mr. LAFALCE, Mrs. MCCARTHY of New York, Mr. MCGOVERN, Ms. CHRISTIAN-GREEN, Mr. FRANK of Massachusetts, and Mr. WEXLER.

H.R. 2456: Mr. ORTIZ.

H.R. 2483: Mr. SCHIFF, Mr. SALMON, and Mr. SUNUNU.

H.R. 2490: Mr. RADANOVICH.

H.R. 2492: Mr. KUCINICH.

H.R. 2497: Mr. RADANOVICH.

H.R. 2499: Ms. CARSON.

H.R. 2503: Mr. CONYERS.

H.R. 2515: Mr. RADANOVICH.

H.R. 2527: Mr. JOHNSON of Wisconsin.

H.R. 2579: Mr. UPTON, Mr. PAUL, Mr. CUNNINGHAM, Mr. PETERSON of Pennsylvania, Mr. SNOWBARGER, and Mr. MCINTOSH.

H.R. 2590: Mr. SANDERS.

H.R. 2593: Ms. WOOLSEY, Mr. KLECZKA, Mr. HALL of Texas, Mr. HANSEN, and Mr. BILBRAY.

H.R. 2596: Mr. LAHOOD, Mr. MANZULLO, Mr. PETRI, Mr. MINGE, Mr. CALVERT, and Mr. FOLEY.

H.R. 2598: Mr. SUNUNU.

H.R. 2625: Mr. HASTERT, Mr. CHAMBLISS, Mr. WAMP, and Mr. BURTON of Indiana.

H.R. 2631: Mr. CALVERT.

H.R. 2667: Mr. CALVERT.

H.R. 2730: Mr. BRYANT, Mr. DUNCAN, Mr. GORDON, Mr. CLEMENT, Mr. WAMP, Mr. JENKINS, and Mr. FORD.

H.R. 2783: Mr. LOBIONDO.

H.R. 2791: Mr. PAPPAS.

H.R. 2796: Mr. WATTS of Oklahoma, Mr. VENTO, Mr. GUTIERREZ, Mr. BURR of North Carolina, Ms. MCKINNEY, Mr. KENNEDY of Rhode Island, Mr. GEJDENSON, Mr. MCINTYRE, Mr. MASCARA, Mr. CALVERT, and Ms. PRYCE of Ohio.

H.R. 2802: Mr. TIERNEY.

H.R. 2820: Mr. TOWNS and Mr. STUPAK.

H.R. 2821: Mr. EWING.

H.R. 2829: Mr. BAKER, Mr. BOEHNER, Mr. BRYANT, Mr. BURR of North Carolina, Mr. CUNNINGHAM, Mr. GOODLING, Mr. GREENWOOD, Mr. LEWIS of California, Mr. NETHERCUTT, Mr. PACKARD, Mr. POMBO, Mr. RIGGS, Mr. ROGERS, Mr. RUSH, Mr. SALMON, Mr. SOLOMON, Mr. WAMP, Mr. WELDON of Florida, Mr. WICKER, and Mr. YOUNG of Florida.

H.R. 2849: Ms. MCCARTHY of Missouri.

H.R. 2850: Mr. FOLEY and Mr. TOWNS.

H.R. 2854: Mr. BENTSEN and Mr. BARRETT of Wisconsin.

H.R. 2864: Mr. GOODLING.

H.R. 2869: Mr. GOODLING.

H.R. 2870: Ms. FURSE.

H.R. 2871: Mr. GOODLING.

H.R. 2873: Mr. GOODLING.

H.R. 2875: Mr. GOODLING.

H.R. 2877: Mr. GOODLING.

H.R. 2879: Mr. GOODLING.

H.R. 2881: Mr. GOODLING.

H.R. 2909: Ms. FURSE and Mr. SHERMAN.

H.R. 2912: Mr. JENKINS, Mr. HILLIARD.

H.R. 2920: Mr. HOUGHTON.

H.R. 2925: Mr. CONYERS.

H.J. Res. 71: Mr. PACKARD.

H. Con. Res. 125: Ms. FURSE.

H. Con. Res. 148: Mr. MENENDEZ and Mr. ENGEL.

H. Con. Res. 174: Mrs. KELLY, Mr. POSHARD, and Mr. CALVERT.

H. Con. Res. 183: Mr. RADANOVICH.

H. Res. 171: Ms. VELAZQUEZ, Mr. WAXMAN, and Mr. MCGOVERN.

H. Res. 267: Mr. CALVERT.

H. Res. 268: Mr. CALVERT.

H. Res. 281: Mr. FAWELL and Mr. PORTER.

H. Res. 310: Mr. WATTS of Oklahoma.

¶129.30 DELETIONS OF SPONSORS FROM PUBLIC BILLS AND RESOLUTIONS

Under clause 4 of rule XXII, sponsors were deleted from public bills and resolutions as follows:

H.R. 600: Mr. PETERSON of Minnesota.

H.R. 1366: Mr. PETERSON of Minnesota.

SUNDAY, NOVEMBER 9, 1997 (130)

¶130.1 DESIGNATION OF SPEAKER PRO TEMPORE

The House was called to order by the SPEAKER pro tempore, Mrs. EMERSON, who laid before the House the following communication:

WASHINGTON, DC,
November 9, 1997.

I hereby designate the Honorable JO ANN EMERSON to act as Speaker pro tempore on this day.

NEWT GINGRICH,
Speaker of the House of Representatives.

¶130.2 APPROVAL OF THE JOURNAL

The SPEAKER pro tempore, Mrs. EMERSON, announced she had examined and approved the Journal of the proceedings of Saturday, November 9, 1997.

Pursuant to clause 1, rule I, the Journal was approved.

Mr. MCNULTY, pursuant to clause 1, rule I, objected to the Chair's approval of the Journal.

The question being put, viva voce,

Will the House agree to the Chair's approval of said Journal?

The SPEAKER pro tempore, Mrs. EMERSON, announced that the yeas had it.

Mr. MCNULTY objected to the vote on the ground that a quorum was not present and not voting.

The SPEAKER pro tempore, Mrs. EMERSON, pursuant to clause 5, rule I, announced that the vote would be postponed until later today.

The point of no quorum was considered as withdrawn.

¶130.3 COMMUNICATIONS

Executive and other communications, pursuant to clause 2, rule XXIV, were referred as follows:

5818. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Corn Gluten; Exemption from the Requirement of a Tolerance [OPP–300505A; FRL–5750–3] (RIN: 2070–AB78) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Agriculture.

5819. A letter from the Assistant Secretary (Installations and Environment), Department of the Navy, transmitting notification of intent to study a commercial or industrial type function performed by 45 or more civilian employees for possible outsourcing, pursuant to 10 U.S.C. 2304 nt.; to the Committee on National Security.

5820. A letter from the Assistant Secretary (Reserve Affairs), Department of Defense, transmitting a report on the progress of the study on the means of ensuring uniformity in provision of medical and dental care for members of reserve components, pursuant to Public Law 104—201, section 746(b) (110 Stat. 2602); to the Committee on National Security.

5821. A letter from the Assistant to the Board, Board of Governors of the Federal Reserve System, transmitting the Board's final rule—Reserve Requirements of Depository Institutions [Regulation D; Docket No. R–0980] received October 31, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Banking and Financial Services.

5822. A letter from the Director, Office of Rulemaking Coordination, Department of Energy, transmitting the Department's ''Major'' final rule— Energy Conservation Program for Consumer Products: Final Rule Regarding Energy Conservation Standards for Room Air Conditioners [Docket Nos. EE-RM–90–201 and EE-RM–93–801–RAC] (RIN: 1904–AA38) received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5823. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Florida [FL–70–1–9738a; FRL–5920–3] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5824. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, South Coast Air Quality Management District [CA 034–0048; FRL–5917–5] received November 7, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5825. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval and Promulgation of Implementation Plans; California State Implementation Plan Revision, San Diego County Air Pollution Control District, Ventura County Air Pollution Control District [CA 083–0053a; FRL–5911–4] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5826. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Michigan: Final Authorization of Revisions to State Hazardous Waste Management Program [FRL–5918–8] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5827. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Ambient Air Quality Surveillance for Lead [AD-FRL–5903–5] (RIN: 2060–AF71) received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5828. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Removal of Requirement in Gasoline Deposit Control Additives Rule Regarding the Identification of the Oxygenate Content of Transferred Gasoline [FRL–5917–9] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5829. A letter from the AMD—Performance Evaluation and RECORDs Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of the Commission's Rules to Establish a Radio Astronomy Coordination Zone in Puerto Rico [ET Docket No. 96–2, RM–8165] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5830. A letter from the AMD—Performance Evaluation and RECORDs Management, Federal Communications Commission, transmitting the Commission's final rule—Amendment of Part 15 of the Commission's Rules to permit operation of biomedical telemetry devices on VHF TV channels 7–13 and on UHF TV channels 14–46 [ET Docket No. 95–177] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5831. A letter from the Director, Regulations Policy and Management Staff, Office of Policy, Food and Drug Administration, transmitting the Administration's final rule—Secondary Direct Food Additives Permitted in Food for Human Consumption; Milk-Clotting Enzymes [Docket No. 93F–0461] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Commerce.

5832. A letter from the Chairman, Nuclear Regulatory Commission, transmitting a report on the nondisclosure of safeguards information for the quarter ending September 30, 1997, pursuant to 42 U.S.C. 2167(e); to the Committee on Commerce.

5833. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Egypt for defense articles and services (Transmittal No. 98–21), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5834. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Navy's Proposed Letter(s) of Offer and Acceptance (LOA) to Korea for defense articles and services (Transmittal No. 98–20), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5835. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office (TECRO) in the United States for defense articles and services (Transmittal No. 98–18), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5836. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Taipei Economic and Cultural Representative Office in the United States for defense articles and services (Transmittal No. 98–16), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5837. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Air Force's proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services (Transmittal No. 98–13), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5838. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Portugal for defense articles and services (Transmittal No. 98–11), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5839. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Turkey for defense articles and services (Transmittal No. 98–09), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5840. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services (Transmittal No. 98–12), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5841. A letter from the Director, Defense Security Assistance Agency, transmitting notification concerning the Department of the Army's Proposed Letter(s) of Offer and Acceptance (LOA) to Greece for defense articles and services (Transmittal No. 98–08), pursuant to 22 U.S.C. 2776(b); to the Committee on International Relations.

5842. A letter from the Director, Defense Security Assistance Agency, transmitting a report of enhancement or upgrade of sensitivity of technology or capability for Saudi Arabia (Transmittal No. A–98), pursuant to 22 U.S.C. 2776(b)(5)(A); to the Committee on International Relations.

5843. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with Canada (Transmittal No. DTC–69–97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5844. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with Germany (Transmittal No. DTC–133–97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5845. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting notification of a proposed manufacturing license agreement for production of major military equipment with the United Kingdom (Transmittal No. DTC–132–97), pursuant to 22 U.S.C. 2776(d); to the Committee on International Relations.

5846. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Germany and Sweden (Transmittal No. DTC–112–97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5847. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Singapore (Transmittal No. DTC–113–97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5848. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Israel (Transmittal No. DTC–97–97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5849. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Japan (Transmittal No. DTC–98–97), pursuant to 22

U.S.C. 2776(c); to the Committee on International Relations.

5850. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to Kuwait (Transmittal No. DTC–114–97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5851. A letter from the Assistant Secretary for Legislative Affairs, Department of State, transmitting certification of a proposed license for the export of defense articles or defense services sold commercially to the United Kingdom (Transmittal No. DTC–117–97), pursuant to 22 U.S.C. 2776(c); to the Committee on International Relations.

5852. A communication from the President of the United States, transmitting the bimonthly report on progress toward a negotiated settlement of the Cyprus question, including any relevant reports from the Secretary General of the United Nations, pursuant to 22 U.S.C. 2373(c); to the Committee on International Relations.

5853. A letter from the Executive Director, Committee for Purchase from People Who Are Blind or Severely Disabled, transmitting the Committee's final rule—Additions to the Procurement List [97–019] received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Government Reform and Oversight.

5854. A letter from the Chairman, Defense Nuclear Facilities Safety Board, transmitting the FY 1997 report pursuant to the Federal Managers' Financial Integrity Act, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5855. A letter from the Chairman, District of Columbia Financial Responsibility and Management Assistance Authority, transmitting the annual report for fiscal year 1997, pursuant to Public Law 104—8; to the Committee on Government Reform and Oversight.

5856. A letter from the Chairman and Chief Executive Officer, Farm Credit Administration, transmitting the semiannual report on the activities of the Office of Inspector General for the period April 1, 1997, through September 30, 1997; and the semiannual management report for the same period, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5857. A letter from the Director, Federal Mediation and Conciliation Service, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100—504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5858. A letter from the Executive Director, Federal Retirement Thrift Investment Board, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100—504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5859. A letter from the President, Institute of American Indian Arts, transmitting the FY 1997 report pursuant to the Federal Managers' Financial Integrity Act, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5860. A letter from the Director, National Gallery of Art, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5861. A letter from the Director, Office of Government Ethics, transmitting the 1997 annual consolidated report in compliance with the Inspector General Act Amendments of 1988 and the Federal Managers' Financial Integrity Act, pursuant to Public Law 100—504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5862. A letter from the Independent Counsel, Office of Independent Counsel, transmitting the 1997 annual report in compliance with the Inspector General Act Amendments of 1988, pursuant to Public Law 100—504, section 104(a) (102 Stat. 2525); to the Committee on Government Reform and Oversight.

5863. A letter from the Director, The Morris K. Udall Foundation, transmitting the annual report pursuant to the Federal Managers' Financial Integrity Act and the Inspector General Act for the year ending September 30, 1997, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5864. A letter from the Acting Director, The Woodrow Wilson Center, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act, pursuant to 5 U.S.C. app. (Insp. Gen. Act) section 5(b); to the Committee on Government Reform and Oversight.

5865. A letter from the President and Chief Executive Officer, United States Enrichment Corporation, transmitting a consolidated report on audit and investigative coverage required by the Inspector General Act of 1978, as amended, and the Federal Managers' Financial Integrity Act covering the year ended September 30, 1997, pursuant to 31 U.S.C. 3512(c)(3); to the Committee on Government Reform and Oversight.

5866. A letter from the President, United States Institute of Peace, transmitting the strategic plan for the period FY 1997 through 2002, pursuant to Public Law 103—62; to the Committee on Government Reform and Oversight.

5867. A letter from the Assistant Secretary, Land and Minerals Management, Department of the Interior, transmitting the Department's final rule—Patent Preparation and Issuance [WO–350–1220–00–24 1A] (RIN: 1004–AC–88) received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

5868. A letter from the Deputy Assistant Administrator for Fisheries, National Oceanic and Atmospheric Administration, transmitting the Administration's final rule—Fisheries of the Exclusive Economic Zone Off Alaska; Insurance Coverage Provisions for Observer Contractors under the North Pacific Interim Groundfish Observer Program [Docket No. 960717195–7255–03; I.D. 100897E] (RIN: 0648–AI95) received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Resources.

5869. A letter from the Assistant Secretary for Employment Standards, Department of Labor, transmitting the Department's final rule—Longshore Act Civil Money Penalties Adjustment (RIN: 1215–AB17) received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on the Judiciary.

5870. A letter from the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, transmitting the Administration's final rule—Temporary Exemption from Chemical Registration for Distributors of Pseudoephedrine and Phenylpropanolamine Products [DEA Number 1681] (RIN: 1117–AA46) received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on the Judiciary.

5871. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval of Modifications to Michigan's Assumed Program to Administer the Section 404 Permitting Program Resulting from the Reorganization of the Michigan Environmental Agencies [FRL–5918–7] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

5872. A letter from the Director, Office of Regulatory Management and Information, Environmental Protection Agency, transmitting the Agency's final rule—Approval of Modifications to Michigan's Approved Program to Administer the National Pollutant Discharge Elimination System Permitting Program Resulting from the Reorganization of the Michigan Environmental Agencies [FRL–5918–6] received November 6, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Transportation and Infrastructure.

5873. A letter from the Director, Office of Regulations Management, Department of Veterans Affairs, transmitting the Department's final rule— Grants to States for Construction or Acquisition of State Home Facilities (RIN: 2900–AI84) received November 9, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Veterans' Affairs.

5874. A letter from the Regulatory Policy Officer, Bureau of Alcohol, Tobacco and Firearms, transmitting the Bureau's final rule—Mendocino Ridge Viticultural Area (RIN: 1512–AA07) received October 30, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5875. A letter from the Assistant Secretary for Employment and Training, Department of Labor, transmitting the Department's final rule—Unemployment Insurance Program Letter [Nos. 41–97 and 44–97] received November 4, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5876. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Material Limitation on Surviving Spouse's Right to Income [Notice 97–63] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

5877. A letter from the Chief, Regulations Unit, Internal Revenue Service, transmitting the Service's final rule—Test of Bankruptcy Appeals Process [Announcement 97–111] received November 8, 1997, pursuant to 5 U.S.C. 801(a)(1)(A); to the Committee on Ways and Means.

¶130.4 MESSAGE FROM THE SENATE

A message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate had passed without amendment bills of the House of the following titles:

H.R. 1086. An Act to codify without substantive change laws related to transportation and to improve the United States Code;

H.R. 1787. An Act to assist in the conservation of Asian elephants by supporting and providing financial resources for the conservation programs of nations within the range of Asian elephants and projects of persons with demonstrated expertise in the conservation of Asian elephants;

H.R. 2731. An Act for the relief of Roy Desmond Moser; and

H.R. 2732. An Act for the relief of John Andre Chalot.

The message also announced that the Senate had passed with amendments in which the concurrence of the House is requested, bills of the House of the following titles:

H.R. 497. An Act to repeal the Federal charter of Group Hospitalization and Medical Services, Inc., and for other purposes; and

H.R. 867. An Act to promote the adoption of children in foster care.

The message also announced that the Senate agrees to the report of the committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 1026) ''An Act to reauthorize the Export-Import Bank of the United States''.

The message also announced that the Senate had passed bills and concurrent resolutions of the following titles, in which the concurrence of the House is requested:

S. 508. An Act to provide for the relief of Mai Hoa ''Jasmin'' Salehi;

S. 759. An Act to amend the State Department Basic Authorities Act of 1956 to require the Secretary of State to submit an annual report to Congress concerning diplomatic immunity;

S. 857. An Act for the relief of Roma Salobrit;

S. 1193. An Act to amend chapter 443 of title 49, United States Code, to extend the authorization of the aviation insurance program, and for other purposes;

S. 1258. An Act to amend the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 to prohibit an alien who is not lawfully present in the United States from receiving assistance under that Act;

S. 1304. An Act for the relief of Belinda McGregor;

S. 1347. An Act to permit the city of Cleveland, Ohio, to convey certain lands that the United States conveyed to the city;

S. 1487. An Act to establish a National Voluntary Mutual Reunion Registry;

S. Con. Res. 58. Concurrent resolution expressing the concern of Congress over Russia's newly passed religion law; and

S. Con. Res. 66. Concurrent resolution to correct the enrollment of S. 399.

¶130.5 SUSPENSION OF THE RULES NOTICE

Mr. SOLOMON pursuant to section 2 of House Resolution 305, at 2:05 p.m. announced the Speaker would recognize Members for motions to suspend the rules under clause 2 of rule XXVII, with respect to the following bills and resolutions that may be considered today: S. 714, Extension and Improvement of the Native American Veteran Housing Loan Pilot Program; S. 1139, Small Business Reauthorization Act of 1997; H.R. 1129, Microcredit for Self-Reliance Act; H. Con. Res. 22, condemning religious persecution in Germany; H. Con. Res. 139, regarding participation in Expo 2000; H. Res. 245, on self-determination for the people of the Western Sahara; H. Con. Res. 156, regarding deterioration of human rights in Afghanistan; H.R. 1377, encouraging retirement income savings; H.R. 2920, immigration entry-exit control system; S. 1231, United States Fire Administration Authorization Act; H.R. 112, conveyance of certain property to Stanislaus County, California; H. R. 1805, Auburn Indian Restoration Act amendments; H.R. 2402, improvement of water-related facilities in Western United States; H.R. 2283, Arches National Park expansion; S. 669, acquisition of the Plains Railroad Depot at the Jimmy Carter National Historic Site; H.R. 2834, Cleveland, Ohio land conveyance; H.R. 2626, Pilot Records Improvement Act of 1996 clarifications; S. 1258, Relocation Assistance and Real Property Acquisition Policies Act amendments; H.R. 2476, to address the needs of families of passengers involved in aircraft accidents; H.R. 1502, to designate the United States Courthouse in Benton, Illinois as the ''James L. Foreman Courthouse''; H.R. 861, Adoption Promotion Act; S. 1026, Export-Import Bank Reauthorization Act; H.R. 2472, Energy Policy and Conservation Act extensions; and the conference report on S. 830, the Food and Drug Administration Modernization and Accountability Act.

¶130.6 PRIVILEGES OF THE HOUSE

Mr. GEPHARDT rose to a question of the privileges of the House and submitted the following resolution (H. Res. 318):

Whereas, the election contest concerning the 46th District of California should be dismissed as there is no credible evidence to show that the outcome of the election is different than the election of Congresswoman Loretta Sanchez.

Whereas, State of California authorities should continue an investigation into any questionable registration activities; and

Whereas, the Committee on House Oversight should examine voter registration procedures; and now therefore be it

Resolved, That the contest in the 46th District of California is dismissed.

The SPEAKER pro tempore, Mrs. EMERSON, ruled that the resolution submitted did present a question of the privileges of the House under rule IX.

Mr. BOEHNER moved to lay the resolution on the table.

The question being put, viva voce,

Will the House lay the resolution on the table?

The SPEAKER pro tempore, Mrs. EMERSON, announced that the yeas had it.

Mr. OBEY objected to the vote on the ground that a quorum was not present and not voting.

A quorum not being present,

The roll was called under clause 4, rule XV, and the call was taken by electronic device.

when their appeared affirmative ..... { Yeas ..... 218; Nays ..... 194; Answered present 1

¶130.7 [Roll No. 622]

YEAS—218

Aderholt	Boehner	Christensen
Archer	Bonilla	Coble
Armey	Brady	Coburn
Bachus	Bryant	Collins
Baker	Bunning	Combest
Ballenger	Burr	Cook
Barr	Burton	Cooksey
Barrett (NE)	Buyer	Cox
Bartlett	Callahan	Crane
Barton	Calvert	Crapo
Bass	Camp	Cunningham
Bateman	Campbell	Davis (VA)
Bereuter	Canady	Deal
Bilbray	Cannon	DeLay
Bilirakis	Castle	Diaz-Balart
Bliley	Chabot	Dickey
Blunt	Chambliss	Doolittle
Boehlert	Chenoweth	Dreier
Duncan	Kingston	Regula
Dunn	Knollenberg	Riggs
Ehlers	Kolbe	Rogan
Ehrlich	LaHood	Rogers
Emerson	Largent	Rohrabacher
English	Latham	Ros-Lehtinen
Ensign	LaTourette	Roukema
Everett	Lazio	Royce
Ewing	Leach	Ryun
Fawell	Lewis (CA)	Salmon
Foley	Lewis (KY)	Sanford
Fossella	Linder	Saxton
Fowler	Livingston	Scarborough
Fox	LoBiondo	Schaefer, Dan
Franks (NJ)	Lucas	Schaffer, Bob
Frelinghuysen	Manzullo	Sensenbrenner
Gallegly	Martinez	Sessions
Ganske	McCollum	Shadegg
Gekas	McCrery	Shaw
Gibbons	McDade	Shays
Gilchrest	McHugh	Shimkus
Gilman	McInnis	Shuster
Goodlatte	McIntosh	Skeen
Goodling	McKeon	Smith (MI)
Goss	Metcalf	Smith (NJ)
Graham	Mica	Smith (OR)
Granger	Miller (FL)	Smith (TX)
Greenwood	Moran (KS)	Smith, Linda
Gutknecht	Morella	Snowbarger
Hansen	Myrick	Solomon
Hastert	Nethercutt	Souder
Hastings (WA)	Neumann	Spence
Hayworth	Ney	Stump
Hefley	Northup	Sununu
Herger	Norwood	Talent
Hill	Nussle	Tauzin
Hilleary	Oxley	Thomas
Hobson	Packard	Thornberry
Horn	Pappas	Thune
Hostettler	Parker	Tiahrt
Houghton	Paul	Traficant
Hulshof	Paxon	Upton
Hunter	Pease	Walsh
Hutchinson	Peterson (PA)	Watkins
Hyde	Petri	Watts (OK)
Inglis	Pickering	Weldon (FL)
Istook	Pitts	Weldon (PA)
Jenkins	Pombo	Weller
Johnson (CT)	Porter	White
Johnson, Sam	Portman	Whitfield
Jones	Pryce (OH)	Wicker
Kasich	Quinn	Wolf
Kelly	Radanovich	Young (AK)
Kim	Ramstad	Young (FL)
King (NY)	Redmond	

NAYS—194

Abercrombie	Dixon	Kanjorski
Allen	Doggett	Kaptur
Andrews	Dooley	Kennedy (MA)
Baesler	Doyle	Kennedy (RI)
Baldacci	Edwards	Kennelly
Barcia	Engel	Kildee
Barrett (WI)	Eshoo	Kilpatrick
Becerra	Etheridge	Kind (WI)
Bentsen	Evans	Klink
Berman	Farr	Kucinich
Berry	Fattah	LaFalce
Bishop	Fazio	Lampson
Blagojevich	Filner	Lantos
Blumenauer	Forbes	Levin
Bonior	Ford	Lewis (GA)
Borski	Frank (MA)	Lipinski
Boswell	Frost	Lofgren
Boucher	Furse	Lowey
Boyd	Gejdenson	Luther
Brown (CA)	Gephardt	Maloney (CT)
Brown (FL)	Goode	Maloney (NY)
Brown (OH)	Gordon	Manton
Cardin	Green	Markey
Carson	Gutierrez	Mascara
Clay	Hall (OH)	Matsui
Clayton	Hall (TX)	McCarthy (MO)
Clement	Hamilton	McCarthy (NY)
Clyburn	Harman	McGovern
Costello	Hastings (FL)	McHale
Coyne	Hefner	McIntyre
Cramer	Hilliard	McKinney
Cummings	Hinchey	McNulty
Danner	Hinojosa	Meehan
Davis (FL)	Holden	Meek
Davis (IL)	Hooley	Menendez
DeFazio	Hoyer	Millender-McDonald
DeGette	Jackson (IL)	Miller (CA)
Delahunt	Jackson-Lee (TX)	Minge
DeLauro	Jefferson	Mink
Dellums	John	Moakley
Deutsch	Johnson (WI)	Mollohan
Dicks	Johnson, E. B.	Moran (VA)
Dingell		

Murtha	Roemer	Stupak
Nadler	Rothman	Tanner
Neal	Roybal-Allard	Tauscher
Oberstar	Rush	Taylor (MS)
Obey	Sabo	Thompson
Olver	Sanchez	Thurman
Ortiz	Sanders	Tierney
Owens	Sandlin	Torres
Pallone	Sawyer	Towns
Pascrell	Scott	Turner
Pastor	Serrano	Velazquez
Payne	Sherman	Vento
Pelosi	Sisisky	Visclosky
Peterson (MN)	Skaggs	Waters
Pickett	Skelton	Watt (NC)
Pomeroy	Slaughter	Waxman
Poshard	Smith, Adam	Wexler
Price (NC)	Snyder	Weygand
Rahall	Spratt	Wise
Rangel	Stabenow	Woolsey
Reyes	Stark	Wynn
Rivers	Stenholm	
Rodriguez	Strickland	

ANSWERED ''PRESENT''—1

Wamp

NOT VOTING—20

Ackerman	Gillmor	Schiff
Bono	Gonzalez	Schumer
Condit	Hoekstra	Stearns
Conyers	Kleczka	Stokes
Cubin	Klug	Taylor (NC)
Flake	McDermott	Yates
Foglietta	Riley	

So the motion to lay the resolution on the table was agreed to.

A motion to reconsider the vote whereby said motion was agreed to was, by unanimous consent, laid on the table.

¶130.8 SUSPENSION OF THE RULES NOTICE

Mr. BEREUTER, pursuant to section 2 of House Resolution 305, at 2:55 p.m. announced the following correction in the bills of the foregoing announcement that the Speaker will recognize Members for motions to suspend the rules under clause 2 of rule XXVII: H.R. 867, instead of H.R. 861.

¶130.9 INTERNATIONAL BROADCASTS TO CHINA

Mr. ROYCE, pursuant to House Resolution 302, called up the bill (H.R. 2232) to provide for increased international broadcasting activities to China.

When said bill was considered and read twice.

Pursuant to House Resolution 302, the following amendment in the nature of a substitute recommended by the Committee on International Relations printed in the bill was considered as agreed to:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Radio Free Asia Act of 1997''.

SEC. 2. FINDINGS.

The Congress makes the following findings:

(1) The Government of the People's Republic of China systematically controls the flow of information to the Chinese people.

(2) The Government of the People's Republic of China demonstrated that maintaining its monopoly on political power is a higher priority than economic development by announcing in January 1996 that its official news agency Xinhua, will supervise wire services selling economic information, including Dow Jones-Telerate, Bloomberg, and Reuters Business, and in announcing in February of 1996 the ''Interim Internet Management Rules'', which have the effect of censoring computer networks.

(3) Under the May 30, 1997, order of Premier Li Peng, all organizations that engage in business activities related to international computer networking must now apply for a license, increasing still further government control over access to the internet.

(4) Both Radio Free Asia and the Voice of America, as a surrogate for a free press in the People's Republic of China, provide an invaluable source of uncensored information to the Chinese people, including objective and authoritative news of in-country and regional events, as well as accurate news about the United States and its policies.

(5) Radio Free Asia currently broadcasts only 5 hours a day in the Mandarin dialect and 2 hours a day in Tibetan.

(6) Voice of America currently broadcasts only 10 hours a day in Mandarin and 3½ hours a day in Tibetan.

(7) Radio Free Asia and Voice of America should develop 24-hour-a-day service in Mandarin, Cantonese, and Tibetan, as well as further broadcasting capability in the dialects spoken in the People's Republic of China.

(8) Radio Free Asia and Voice of America, in working toward continuously broadcasting to the People's Republic of China in multiple languages, have the capability to immediately establish 24-hour-a-day Mandarin broadcasting to that nation by staggering the hours of Radio Free Asia and Voice of America.

(9) Simultaneous broadcasting on Voice of America radio and Worldnet television 7 days a week in Mandarin are also important and needed capabilities.

SEC. 3. AUTHORIZATION OF APPROPRIATIONS FOR INCREASED FUNDING FOR RADIO FREE ASIA AND VOICE OF AMERICA BROADCASTING TO CHINA.

(a) AUTHORIZATION OF APPROPRIATIONS FOR RADIO FREE ASIA—

(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for ''Radio Free Asia'' $30,000,000 for fiscal year 1998 and $22,000,000 for fiscal year 1999.

(2) LIMITATIONS.—

(A) Of the funds under paragraph (1) authorized to be appropriated for fiscal year 1998, $8,000,000 is authorized to be appropriated for one-time capital costs.

(B) Of the funds under paragraph (1), $700,000 is authorized to be appropriated for each such fiscal year for additional personnel to staff Cantonese language broadcasting.

(b) AUTHORIZATION OF APPROPRIATIONS FOR INTERNATIONAL BROADCASTING TO CHINA AND NORTH KOREA.—In addition to such sums as are otherwise authorized to be appropriated for ''International Broadcasting Activities'' for fiscal years 1998 and 1999, there are authorized to be appropriated for ''International Broadcasting Activities'' $10,000,000 for fiscal year 1998 and $7,000,000 for fiscal year 1999, which shall be available only for enhanced Voice of America broadcasting to China and North Korea.

(c) AUTHORIZATION OF APPROPRIATIONS FOR RADIO CONSTRUCTION.—

(1) AUTHORIZATION OF APPROPRIATIONS.—In addition to such sums as are otherwise authorized to be appropriated for ''Radio Construction'' for fiscal years 1998 and 1999, there are authorized to be appropriated for ''Radio Construction'' $10,000,000 for fiscal year 1998 and $3,000,000 for fiscal year 1999, which shall be available only for construction in support of enhanced broadcasting to China.

(2) LIMITATION.—Of the funds under paragraph (1) authorized to be appropriated for fiscal year 1998, $3,000,000 is authorized to be appropriated to facilitate the timely augmentation of transmitters at Tinian, the Commonwealth of the Northern Mariana Islands.

(d) ALLOCATION.—Of the amounts authorized to be appropriated for ''International Broadcasting Activities'', the Director of the United States Information Agency and the Board of Broadcasting Governors shall seek to ensure that the amounts made available for broadcasting to nations whose people do not fully enjoy freedom of expression do not decline in proportion to the amounts made available for broadcasting to other nations.

(e) ALLOCATION OF FUNDS FOR NORTH KOREA.—Of the funds under subsection (b), $2,000,000 is authorized to be appropriated for each fiscal year for additional personnel and broadcasting targeted at North Korea.

SEC. 4. REPORTING REQUIREMENT.

Not later than 90 days after the date of enactment of this Act, in consultation with the Board of Broadcasting Governors, the President shall prepare and transmit to Congress a report on a plan to achieve continuous broadcasting of Radio Free Asia and Voice of America to the People's Republic of China in multiple major dialects and languages.

SEC. 5. UTILIZATION OF UNITED STATES INTERNATIONAL BROADCASTING SERVICES FOR PUBLIC SERVICE ANNOUNCEMENTS REGARDING FUGITIVES FROM UNITED STATES JUSTICE.

United States international broadcasting services, particularly the Voice of America, shall produce and broadcast public service announcements, by radio, television, and Internet, regarding fugitives from the criminal justice system of the United States, including cases of international child abduction.

After debate,

Pursuant to House Resolution 302, the previous question was ordered.

The bill, as amended, was ordered to be engrossed and read a third time, was read a third time by title.

The question being put, viva voce,

Will the House pass said bill?

The SPEAKER pro tempore, Mrs. EMERSON, announced that the yeas had it.

Mr. ROYCE demanded that the vote be taken by the yeas and nays, which demand was supported by one-fifth of the Members present, so the yeas and nays were ordered.

The SPEAKER pro tempore, Mrs. EMERSON, pursuant to clause 5, rule I, announced that further proceedings on the question of passage of said bill were postponed.

¶130.10 DESIGNATION OF SPEAKER PRO TEMPORE TO SIGN ENROLLMENTS

The SPEAKER pro tempore, Mrs. EMERSON, laid before the House a communication, which was read as follows:

WASHINGTON, DC,
November 9, 1997.

I hereby designate the Honorable CONSTANCE A. MORELLA to act as Speaker pro tempore to sign enrolled bills and joint resolutions for the remainder of the first session of the One Hundred Fifth Congress.

NEWT GINGRICH,
Speaker of the House of Representatives.

By unanimous consent, the designation was accepted.

¶130.11 PUBLIC WORKS PROJECTS

The SPEAKER pro tempore, Mrs. EMERSON, laid before the House a communication, which was read as follows:

Washington, DC, November 4, 1997.

Hon. NEWT GINGRICH,

Speaker, United States House of Representatives, Capitol Building, Washington, DC.

DEAR SPEAKER GINGRICH: On Wednesday, October 29, 1997, the Committee on Transportation and Infrastructure, pursuant to 40 U.S.C. §606, approved fifteen resolutions authorizing appropriations for federal buildings and leased space. Please find enclosed copies of these resolutions.

With warm regards, I remain,

Sincerely,

BUD SHUSTER,
Chairman.

The communication, together with the accompanying papers, was referred to the Committee on Appropriations.

¶130.12 HOMELESS VETERANS ACT

Mr. STUMP moved to suspend the rules and pass the bill of the Senate (S. 714) to extend and improve the Native American Veteran Housing Loan Pilot Program of the Department of Veterans Affairs, to extend certain authorities of the Secretary of Veterans Affairs relating to services for homeless veterans, to extend certain other authorities of the Secretary, and for other purposes; as amended.

The SPEAKER pro tempore, Mrs. EMERSON, recognized Mr. STUMP and Mr. EVANS, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. LATHAM, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

By unanimous consent, the title was amended so as to read: ''An Act to amend title 38, United States Code, to revise, extend, and improve programs for veterans.''.

A motion to reconsider the votes whereby the rules were suspended and said bill, as amended, was passed and the title was amended was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said amendments.

¶130.13 SUSPENSION OF THE RULES NOTICE

Mr. TALENT, pursuant to section 2 of House Resolution 305, at 4:23 p.m. announced the following correction in the bills of the announcement of earlier today that the Speaker will recognize Members for motions to suspend the rules under clause 2 of rule XXVII: S. 1347, instead of H.R. 2834.

¶130.14 SMALL BUSINESS REAUTHORIZATION

Mr. TALENT moved to suspend the rules and agree to the following amendment of the Senate to the amendment of the House to the text of the bill (S. 1139) to reauthorize the programs of the Small Business Administration, and for other purposes:

In lieu of the matter proposed to be inserted by the House amendment to the text of the bill, insert:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Small Business Reauthorization Act of 1997''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. DEFINITIONS.

In this Act—

(1) the term ''Administration'' means the Small Business Administration;

(2) the term ''Administrator'' means the Administrator of the Small Business Administration;

(3) the term ''Committees'' means the Committees on Small Business of the House of Representatives and the Senate; and

(4) the term ''small business concern'' has the meaning given the term in section 3 of the Small Business Act (15 U.S.C. 632).

SEC. 3. EFFECTIVE DATE.

This Act and the amendments made by this Act shall take effect on October 1, 1997.

TITLE I—AUTHORIZATIONS

SEC. 101. AUTHORIZATIONS.

Section 20 of the Small Business Act (15 U.S.C. 631 note) is amended by striking subsections (c) through (q) and inserting the following:

''(c) FISCAL YEAR 1998.—

''(1) PROGRAM LEVELS.—The following program levels are authorized for fiscal year 1998:

''(A) For the programs authorized by this Act, the Administration is authorized to make—

''(i) $40,000,000 in technical assistance grants, as provided in section 7(m); and

''(ii) $60,000,000 in direct loans, as provided in section 7(m).

''(B) For the programs authorized by this Act, the Administration is authorized to make $16,040,000,000 in deferred participation loans and other financings. Of such sum, the Administration is authorized to make—

''(i) $12,000,000,000 in general business loans as provided in section 7(a);

''(ii) $3,000,000,000 in financings as provided in section 7(a)(13) of this Act and section 504 of the Small Business Investment Act of 1958;

''(iii) $1,000,000,000 in loans as provided in section 7(a)(21); and

''(iv) $40,000,000 in loans as provided in section 7(m).

''(C) For the programs authorized by title III of the Small Business Investment Act of 1958, the Administration is authorized to make—

''(i) $700,000,000 in purchases of participating securities; and

''(ii) $600,000,000 in guarantees of debentures.

''(D) For the programs authorized by part B of title IV of the Small Business Investment Act of 1958, the Administration is authorized to enter into guarantees not to exceed $2,000,000,000, of which not more than $650,000,000 may be in bonds approved pursuant to section 411(a)(3) of that Act.

''(E) The Administration is authorized to make grants or enter into cooperative agreements—

''(i) for the Service Corps of Retired Executives program authorized by section 8(b)(1), $4,000,000; and

''(ii) for activities of small business development centers pursuant to section 21(c)(3)(G), $15,000,000, to remain available until expended.

''(2) ADDITIONAL AUTHORIZATIONS.—

''(A) There are authorized to be appropriated to the Administration for fiscal year 1998 such sums as may be necessary to carry out this Act, including administrative expenses and necessary loan capital for disaster loans pursuant to section 7(b), and to carry out the Small Business Investment Act of 1958, including salaries and expenses of the Administration.

''(B) Notwithstanding subparagraph (A), for fiscal year 1998—

''(i) no funds are authorized to be provided to carry out the loan program authorized by section 7(a)(21) except by transfer from another Federal department or agency to the Administration, unless the program level authorized for general business loans under paragraph (1)(B)(i) is fully funded; and

''(ii) the Administration may not approve loans on behalf of the Administration or on behalf of any other department or agency, by contract or otherwise, under terms and conditions other than those specifically authorized under this Act or the Small Business Investment Act of 1958, except that it may approve loans under section 7(a)(21) of this Act in gross amounts of not more than $1,250,000.

''(d) FISCAL YEAR 1999.—

''(1) PROGRAM LEVELS.—The following program levels are authorized for fiscal year 1999:

''(A) For the programs authorized by this Act, the Administration is authorized to make—

''(i) $40,000,000 in technical assistance grants as provided in section 7(m); and

''(ii) $60,000,000 in direct loans, as provided in section 7(m).

''(B) For the programs authorized by this Act, the Administration is authorized to make $17,540,000,000 in deferred participation loans and other financings. Of such sum, the Administration is authorized to make—

''(i) $13,000,000,000 in general business loans as provided in section 7(a);

''(ii) $3,500,000,000 in financings as provided in section 7(a)(13) of this Act and section 504 of the Small Business Investment Act of 1958;

''(iii) $1,000,000,000 in loans as provided in section 7(a)(21); and

''(iv) $40,000,000 in loans as provided in section 7(m).

''(C) For the programs authorized by title III of the Small Business Investment Act of 1958, the Administration is authorized to make—

''(i) $800,000,000 in purchases of participating securities; and

''(ii) $700,000,000 in guarantees of debentures.

''(D) For the programs authorized by part B of title IV of the Small Business Investment Act of 1958, the Administration is authorized to enter into guarantees not to exceed $2,000,000,000, of which not more than $650,000,000 may be in bonds approved pursuant to section 411(a)(3) of that Act.

''(E) The Administration is authorized to make grants or enter cooperative agreements—

''(i) for the Service Corps of Retired Executives program authorized by section 8(b)(1), $4,500,000; and

''(ii) for activities of small business development centers pursuant to section 21(c)(3)(G), not to exceed $15,000,000, to remain available until expended.

''(2) ADDITIONAL AUTHORIZATIONS.—

''(A) There are authorized to be appropriated to the Administration for fiscal year 1999 such sums as may be necessary to carry out this Act, including administrative expenses and necessary loan capital for disaster loans pursuant to section 7(b), and to carry out the Small Business Investment Act of 1958, including salaries and expenses of the Administration.

''(B) Notwithstanding subparagraph (A), for fiscal year 1999—

''(i) no funds are authorized to be provided to carry out the loan program authorized by section 7(a)(21) except by transfer from another Federal department or agency to the Administration, unless the program level authorized for general business loans under paragraph (1)(B)(i) is fully funded; and

''(ii) the Administration may not approve loans on behalf of the Administration or on behalf of any other department or agency, by contract or otherwise, under terms and conditions other than those specifically authorized under this Act or the Small Business Investment Act of 1958, except that it may approve loans under section 7(a)(21) of this Act in gross amounts of not more than $1,250,000.

''(e) FISCAL YEAR 2000.—

''(1) PROGRAM LEVELS.—The following program levels are authorized for fiscal year 2000:

''(A) For the programs authorized by this Act, the Administration is authorized to make—

''(i) $40,000,000 in technical assistance grants as provided in section 7(m); and

''(ii) $60,000,000 in direct loans, as provided in section 7(m).

''(B) For the programs authorized by this Act, the Administration is authorized to make $20,040,000,000 in deferred participation loans and other financings. Of such sum, the Administration is authorized to make—

''(i) $14,500,000,000 in general business loans as provided in section 7(a);

''(ii) $4,500,000,000 in financings as provided in section 7(a)(13) of this Act and section 504 of the Small Business Investment Act of 1958;

''(iii) $1,000,000,000 in loans as provided in section 7(a)(21); and

''(iv) $40,000,000 in loans as provided in section 7(m).

''(C) For the programs authorized by title III of the Small Business Investment Act of 1958, the Administration is authorized to make—

''(i) $900,000,000 in purchases of participating securities; and

''(ii) $800,000,000 in guarantees of debentures.

''(D) For the programs authorized by part B of title IV of the Small Business Investment Act of 1958, the Administration is authorized to enter into guarantees not to exceed $2,000,000,000, of which not more than $650,000,000 may be in bonds approved pursuant to section 411(a)(3) of that Act.

''(E) The Administration is authorized to make grants or enter cooperative agreements—

''(i) for the Service Corps of Retired Executives program authorized by section 8(b)(1), $5,000,000; and

''(ii) for activities of small business development centers pursuant to section 21(c)(3)(G), not to exceed $15,000,000, to remain available until expended.

''(2) ADDITIONAL AUTHORIZATIONS.—

''(A) There are authorized to be appropriated to the Administration for fiscal year 2000 such sums as may be necessary to carry out this Act, including administrative expenses and necessary loan capital for disaster loans pursuant to section 7(b), and to carry out the Small Business Investment Act of 1958, including salaries and expenses of the Administration.

''(B) Notwithstanding subparagraph (A), for fiscal year 2000—

''(i) no funds are authorized to be provided to carry out the loan program authorized by section 7(a)(21) except by transfer from another Federal department or agency to the Administration, unless the program level authorized for general business loans under paragraph (1)(B)(i) is fully funded; and

''(ii) the Administration may not approve loans on behalf of the Administration or on behalf of any other department or agency, by contract or otherwise, under terms and conditions other than those specifically authorized under this Act or the Small Business Investment Act of 1958, except that it may approve loans under section 7(a)(21) of this Act in gross amounts of not more than $1,250,000.''.

TITLE II—FINANCIAL ASSISTANCE

Subtitle A—Microloan Program

SEC. 201. MICROLOAN PROGRAM.

(a) LOAN LIMITS.—Section 7(m)(3)(C) of the Small Business Act (15 U.S.C. 636(m)(3)(C)) is amended by striking ''$2,500,000'' and inserting ''$3,500,000''.

(b) LOAN LOSS RESERVE FUND.—Section 7(m)(3)(D) of the Small Business Act (15 U.S.C. 636(m)(3)(D)) is amended by striking clauses (i) and (ii), and inserting the following:

''(i) during the initial 5 years of the intermediary's participation in the program under this subsection, at a level equal to not more than 15 percent of the outstanding balance of the notes receivable owed to the intermediary; and

''(ii) in each year of participation thereafter, at a level equal to not more than the greater of—

''(I) 2 times an amount reflecting the total losses of the intermediary as a result of participation in the program under this subsection, as determined by the Administrator on a case-by-case basis; or

''(II) 10 percent of the outstanding balance of the notes receivable owed to the intermediary.''.

(c) AUTHORIZATION OF APPROPRIATIONS.—Section 7(m) of the Small Business Act (15 U.S.C. 636(m)) is amended—

(1) in the subsection heading, by striking ''DEMONSTRATION'';

(2) by striking ''Demonstration'' each place that term appears;

(3) by striking ''demonstration'' each place that term appears; and

(4) in paragraph (12), by striking ''during fiscal years 1995 through 1997'' and inserting ''during fiscal years 1998 through 2000''.

(d) TECHNICAL ASSISTANCE GRANTS.—Section 7(m) of the Small Business Act (15 U.S.C. 636(m)) is amended—

(1) in paragraph (4)(E)—

(A) by striking ''Each intermediary'' and inserting the following:

''(i) IN GENERAL.—Each intermediary'';

(B) by striking ''15'' and inserting ''25''; and

(C) by adding at the end the following:

''(ii) TECHNICAL ASSISTANCE.—An intermediary may expend not more than 25 percent of the funds received under paragraph (1)(B)(ii) to enter into third party contracts for the provision of technical assistance.''; and

(2) in paragraph (5)(A)—

(A) by striking ''in each of the 5 years of the demonstration program established under this subsection,''; and

(B) by striking ''for terms of up to 5 years'' and inserting ''annually''.

SEC. 202. WELFARE-TO-WORK MICROLOAN INITIATIVE.

(a) INITIATIVE.—Section 7(m) of the Small Business Act (15 U.S.C. 636(m)) is amended—

(1) in paragraph (1)(A)—

(A) in clause (ii), by striking ''and'' at the end;

(B) in clause (iii), by striking the period at the end and inserting ''; and''; and

(C) by adding at the end the following:

''(iv) to establish a welfare-to-work microloan initiative, which shall be administered by the Administration, in order to test the feasibility of supplementing the technical assistance grants provided under clauses (ii) and (iii) of subparagraph (B) to individuals who are receiving assistance under the State program funded under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.), or under any comparable State funded means tested program of assistance for low-income individuals, in order to adequately assist those individuals in—

''(I) establishing small businesses; and

''(II) eliminating their dependence on that assistance.'';

(2) in paragraph (4), by adding at the end the following:

''(F) SUPPLEMENTAL GRANT.—

''(i) IN GENERAL.—The Administration may accept any funds transferred to the Administration from other departments or agencies of the Federal Government to make grants in accordance with this subparagraph and section 202(b) of the Small Business Reauthorization Act of 1997 to participating intermediaries and technical assistance providers under paragraph (5), for use in accordance with clause (iii) to provide additional technical assistance and related services to recipients of assistance under a State program described in paragraph (1)(A)(iv) at the time they initially apply for assistance under this subparagraph.

''(ii) ELIGIBLE RECIPIENTS; GRANT AMOUNTS.—In making grants under this subparagraph, the Administration may select, from among participating intermediaries and technical assistance providers described in clause (i), not more than 20 grantees in fiscal year 1998, not more than 25 grantees in fiscal year 1999, and not more than 30 grantees in fiscal year 2000, each of whom may receive a grant under this subparagraph in an amount not to exceed $200,000 per year.

''(iii) USE OF GRANT AMOUNTS.—Grants under this subparagraph—

''(I) are in addition to other grants provided under this subsection and shall not require the contribution of matching amounts as a condition of eligibility; and

''(II) may be used by a grantee—

''(aa) to pay or reimburse a portion of child care and transportation costs of recipients of assistance described in clause (i), to the extent such costs are not otherwise paid by State block grants under the Child Care Development Block Grant Act of 1990 (42 U.S.C. 9858 et seq.) or under part A of title IV of the Social Security Act (42 U.S.C. 601 et seq.); and

''(bb) for marketing, management, and technical assistance to recipients of assistance described in clause (i).

''(iv) MEMORANDUM OF UNDERSTANDING.—Prior to accepting any transfer of funds under clause (i) from a department or agency of the Federal Government, the Administration shall enter into a Memorandum of Understanding with the department or agency, which shall—

''(I) specify the terms and conditions of the grants under this subparagraph; and

''(II) provide for appropriate monitoring of expenditures by each grantee under this subparagraph and each recipient of assistance described in clause (i) who receives assistance from a grantee under this subparagraph, in order to ensure compliance with this subparagraph by those grantees and recipients of assistance.'';

(3) in paragraph (6), by adding at the end the following:

''(E) ESTABLISHMENT OF CHILD CARE OR TRANSPORTATION BUSINESSES.—In addition to other eligible small businesses concerns, borrowers under any program under this subsection may include individuals who will use the loan proceeds to establish for-profit or nonprofit child care establishments or businesses providing for-profit transportation services.'';

(4) in paragraph (9)—

(A) by striking the paragraph designation and paragraph heading and inserting the following:

''(9) GRANTS FOR MANAGEMENT, MARKETING, TECHNICAL ASSISTANCE, AND RELATED SERVICES.—''; and

(B) by adding at the end the following:

''(C) WELFARE-TO-WORK MICROLOAN INITIATIVE.—Of amounts made available to carry out the welfare-to-work microloan initiative under paragraph (1)(A)(iv) in any fiscal year, the Administration may use not more than 5 percent to provide technical assistance, either directly or through contractors, to welfare-to-work microloan initiative grantees, to ensure that, as grantees, they have the knowledge, skills, and understanding of microlending and welfare-to-work transition, and other related issues, to operate a successful welfare-to-work microloan initiative.''; and

(5) by adding at the end the following:

''(13) EVALUATION OF WELFARE-TO-WORK MICROLOAN INITIATIVE.—On January 31, 1999, and annually thereafter, the Administration shall submit to the Committees on Small Business of the House of Representatives and the Senate a report on any monies distributed pursuant to paragraph (4)(F).''.

(b) TRANSFER OF FUNDS.—

(1) IN GENERAL.—No funds are authorized to be appropriated or otherwise provided to carry out the grant program under section 7(m)(4)(F) of the Small Business Act (15 U.S.C. 636(m)(4)(F)) (as added by this section), except by transfer from another department or agency of the Federal Government to the Administration in accordance with this subsection.

(2) LIMITATION ON AMOUNTS.—The total amount transferred to the Administration from other departments and agencies of the Federal Government to carry out the grant program under section 7(m)(4)(F) of the Small Business Act (15 U.S.C. 636(m)(4)(F)) (as added by this section) shall not exceed—

(A) $3,000,000 for fiscal year 1998;

(B) $4,000,000 for fiscal year 1999; and

(C) $5,000,000 for fiscal year 2000.

Subtitle B—Small Business Investment Company Program

SEC. 211. 5-YEAR COMMITMENTS FOR SBICs AT OPTION OF ADMINISTRATOR.

Section 20(a)(2) of the Small Business Act (15 U.S.C. 631 note) is amended in the last sentence by striking ''the following fiscal year'' and inserting ''any 1 or more of the 4 subsequent fiscal years''.

SEC. 212. UNDERSERVED AREAS.

Section 301(c)(4)(B) of the Small Business Investment Act of 1958 (15 U.S.C. 681(c)(4)(B)) is amended to read as follows:

''(B) LEVERAGE.—An applicant licensed pursuant to the exception provided in this paragraph shall not be eligible to receive leverage as a licensee until the applicant satisfies the requirements of section 302(a), unless the applicant—

''(i) files an application for a license not later than 180 days after the date of enactment of the Small Business Reauthorization Act of 1997;

''(ii) is located in a State that is not served by a licensee; and

''(iii) agrees to be limited to 1 tier of leverage available under section 302(b), until the applicant meets the requirements of section 302(a).''.

SEC. 213. PRIVATE CAPITAL.

Section 103(9)(B)(iii) of the Small Business Investment Act of 1958 (15 U.S.C. 662(9)(B)(iii)) is amended—

(1) by redesignating subclauses (I) and (II) as subclauses (II) and (III), respectively; and

(2) by inserting before subclause (II) (as redesignated) the following:

''(I) funds obtained from the business revenues (excluding any governmental appropriation) of any federally chartered or government-sponsored corporation established prior to October 1, 1987;''.

SEC. 214. FEES.

Section 301 of the Small Business Investment Act of 1958 (15 U.S.C. 681) is amended by adding at the end the following:

''(e) FEES.—

''(1) IN GENERAL.—The Administration may prescribe fees to be paid by each applicant for a license to operate as a small business investment company under this Act.

''(2) USE OF AMOUNTS.—Fees collected under this subsection—

''(A) shall be deposited in the account for salaries and expenses of the Administration; and

''(B) are authorized to be appropriated solely to cover the costs of licensing examinations.''.

SEC. 215. SMALL BUSINESS INVESTMENT COMPANY PROGRAM REFORM.

(a) BANK INVESTMENTS.—Section 302(b) of the Small Business Investment Act of 1958 (15 U.S.C. 682(b)) is amended by striking ''1956,'' and all that follows before the period and inserting the following: ''1956, any national bank, or any member bank of the Federal Reserve System or nonmember insured bank to the extent permitted under applicable State law, may invest in any 1 or more small business investment companies, or in any entity established to invest solely in small business investment companies, except that in no event shall the total amount of such investments of any such bank exceed 5 percent of the capital and surplus of the bank''.

(b) INDEXING FOR LEVERAGE.—Section 303 of the Small Business Investment Act of 1958 (15 U.S.C. 683) is amended—

(1) in subsection (b)—

(A) in paragraph (2), by adding at the end the following:

''(D)(i) The dollar amounts in subparagraphs (A), (B), and (C) shall be adjusted annually to reflect increases in the Consumer Price Index established by the Bureau of Labor Statistics of the Department of Labor.

''(ii) The initial adjustments made under this subparagraph after the date of enactment of the Small Business Reauthorization Act of 1997 shall reflect only increases from March 31, 1993.''; and

(B) by striking paragraph (4) and inserting the following:

''(4) MAXIMUM AGGREGATE AMOUNT OF LEVERAGE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), the aggregate amount of outstanding leverage issued to any company or companies that are commonly controlled

(as determined by the Administrator) may not exceed $90,000,000, as adjusted annually for increases in the Consumer Price Index.

''(B) EXCEPTIONS.—The Administrator may, on a case-by-case basis—

''(i) approve an amount of leverage that exceeds the amount described in subparagraph (A) for companies under common control; and

''(ii) impose such additional terms and conditions as the Administrator determines to be appropriate to minimize the risk of loss to the Administration in the event of default.

''(C) APPLICABILITY OF OTHER PROVISIONS.—Any leverage that is issued to a company or companies commonly controlled in an amount that exceeds $90,000,000, whether as a result of an increase in the Consumer Price Index or a decision of the Administrator, is subject to subsection (d).''; and

(2) by striking subsection (d) and inserting the following:

''(d) REQUIRED CERTIFICATIONS.—

''(1) IN GENERAL.—The Administrator shall require each licensee, as a condition of approval of an application for leverage, to certify in writing—

''(A) for licensees with leverage less than or equal to $90,000,000, that not less than 20 percent of the licensee's aggregate dollar amount of financings will be provided to smaller enterprises; and

''(B) for licensees with leverage in excess of $90,000,000, that, in addition to satisfying the requirements of subparagraph (A), 100 percent of the licensee's aggregate dollar amount of financings made in whole or in part with leverage in excess of $90,000,000 will be provided to smaller enterprises (as defined in section 103(12)).

''(2) MULTIPLE LICENSEES.—Multiple licensees under common control (as determined by the Administrator) shall be considered to be a single licensee for purposes of determining both the applicability of and compliance with the investment percentage requirements of this subsection.''.

(c) TAX DISTRIBUTIONS.—Section 303(g)(8) of the Small Business Investment Act of 1958 (15 U.S.C. 683(g)(8)) is amended by adding at the end the following: ''A company may also elect to make a distribution under this paragraph at the end of any calendar quarter based on a quarterly estimate of the maximum tax liability. If a company makes 1 or more quarterly distributions for a calendar year, and the aggregate amount of those distributions exceeds the maximum amount that the company could have distributed based on a single annual computation, any subsequent distribution by the company under this paragraph shall be reduced by an amount equal to the excess amount distributed.''.

(d) LEVERAGE FEE.—Section 303(i) of the Small Business Investment Act of 1958 (15 U.S.C. 683(i)) is amended by striking '', payable upon'' and all that follows before the period and inserting the following: ''in the following manner: 1 percent upon the date on which the Administration enters into any commitment for such leverage with the licensee, and the balance of 2 percent (or 3 percent if no commitment has been entered into by the Administration) on the date on which the leverage is drawn by the licensee''.

(e) PERIODIC ISSUANCE OF GUARANTEES AND TRUST CERTIFICATES.—Section 320 of the Small Business Investment Act of 1958 (15 U.S.C. 687m) is amended by striking ''three months'' and inserting ''6 months''.

SEC. 216. EXAMINATION FEES.

Section 310(b) of the Small Business Investment Act of 1958 (15 U.S.C. 687b(b)) is amended by inserting after the first sentence the following: ''Fees collected under this subsection shall be deposited in the account for salaries and expenses of the Administration, and are authorized to be appropriated solely to cover the costs of examinations and other program oversight activities.''.

Subtitle C—Certified Development Company Program

SEC. 221. LOANS FOR PLANT ACQUISITION, CONSTRUCTION, CONVERSION, AND EXPANSION.

Section 502 of the Small Business Investment Act of 1958 (15 U.S.C. 696) is amended—

(1) by striking paragraph (1) and inserting the following:

''(1) USE OF PROCEEDS.—The proceeds of any such loan shall be used solely by the borrower to assist 1 or more identifiable small business concerns and for a sound business purpose approved by the Administration.'';

(2) in paragraph (3), by adding at the end the following:

''(D) SELLER FINANCING.—Seller-provided financing may be used to meet the requirements of subparagraph (B), if the seller subordinates the interest of the seller in the property to the debenture guaranteed by the Administration.

''(E) COLLATERALIZATION.—The collateral provided by the small business concern shall generally include a subordinate lien position on the property being financed under this title, and is only 1 of the factors to be evaluated in the credit determination. Additional collateral shall be required only if the Administration determines, on a case by case basis, that additional security is necessary to protect the interest of the Government.''; and

(3) by adding at the end the following:

''(5) LIMITATION ON LEASING.—In addition to any portion of the project permitted to be leased under paragraph (4), not to exceed 20 percent of the project may be leased by the assisted small business to 1 or more other tenants, if the assisted small business occupies permanently and uses not less than a total of 60 percent of the space in the project after the execution of any leases authorized under this section.''.

SEC. 222. DEVELOPMENT COMPANY DEBENTURES.

Section 503 of the Small Business Investment Act of 1958 (15 U.S.C. 697) is amended—

(1) in subsection (b)(7), by striking subparagraph (A) and inserting the following:

''(A) assesses and collects a fee, which shall be payable by the borrower, in an amount established annually by the Administration, which amount shall not exceed the lesser of—

''(i) 0.9375 percent per year of the outstanding balance of the loan; and

''(ii) the minimum amount necessary to reduce the cost (as defined in section 502 of the Federal Credit Reform Act of 1990) to the Administration of purchasing and guaranteeing debentures under this Act to zero; and''; and

(2) in subsection (f), by striking ''1997'' and inserting ''2000''.

SEC. 223. PREMIER CERTIFIED LENDERS PROGRAM.

(a) IN GENERAL.—Section 508 of the Small Business Investment Act of 1958 (15 U.S.C. 697e) is amended—

(1) in subsection (a), by striking ''not more than 15'';

(2) in subsection (b)—

(A) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking ''if such company'';

(ii) by striking subparagraphs (A) and (B) and inserting the following:

''(A) if the company is an active certified development company in good standing and has been an active participant in the accredited lenders program during the entire 12-month period preceding the date on which the company submits an application under paragraph (1), except that the Administration may waive this requirement if the company is qualified to participate in the accredited lenders program;

''(B) if the company has a history of—

''(i) submitting to the Administration adequately analyzed debenture guarantee application packages; and

''(ii) of properly closing section 504 loans and servicing its loan portfolio;'';

(iii) in subparagraph (C)—

(I) by inserting ''if the company'' after ''(C)''; and

(II) by striking the period at the end and inserting ''; and''; and

(iv) by adding at the end the following:

''(D) the Administrator determines, with respect to the company, that the loss reserve established in accordance with subsection (c)(2) is sufficient for the company to meet its obligations to protect the Federal Government from risk of loss.''; and

(B) by adding at the end the following:

''(3) APPLICABILITY OF CRITERIA AFTER DESIGNATION.—The Administrator may revoke the designation of a certified development company as a premier certified lender under this section at any time, if the Administrator determines that the certified development company does not meet any requirement described in subparagraphs (A) through (D) of paragraph (2).'';

(3) by striking subsection (c) and inserting the following:

''(c) LOSS RESERVE.—

''(1) ESTABLISHMENT.—A company designated as a premier certified lender shall establish a loss reserve for financing approved pursuant to this section.

''(2) AMOUNT.—The amount of each loss reserve established under paragraph (1) shall be 10 percent of the amount of the company's exposure, as determined under subsection (b)(2)(C).

''(3) ASSETS.—Each loss reserve established under paragraph (1) shall be comprised of—

''(A) segregated funds on deposit in an account or accounts with a federally insured depository institution or institutions selected by the company, subject to a collateral assignment in favor of, and in a format acceptable to, the Administration;

''(B) irrevocable letter or letters of credit, with a collateral assignment in favor of, and a commercially reasonable format acceptable to, the Administration; or

''(C) any combination of the assets described in subparagraphs (A) and (B).

''(4) CONTRIBUTIONS.—The company shall make contributions to the loss reserve, either cash or letters of credit as provided above, in the following amounts and at the following intervals:

''(A) 50 percent when a debenture is closed.

''(B) 25 percent additional not later than 1 year after a debenture is closed.

''(C) 25 percent additional not later than 2 years after a debenture is closed.

''(5) REPLENISHMENT.—If a loss has been sustained by the Administration, any portion of the loss reserve, and other funds provided by the premier company as necessary, may be used to reimburse the Administration for the premier company's 10 percent share of the loss as provided in subsection (b)(2)(C). If the company utilizes the reserve, within 30 days it shall replace an equivalent amount of funds.

''(6) DISBURSEMENTS.—The Administration shall allow the certified development company to withdraw from the loss reserve amounts attributable to any debenture that has been repaid.'';

(4) in subsection (d)(1), by striking ''to approve loans'' and inserting ''to approve, authorize, close, service, foreclose, litigate (except that the Administration may monitor the conduct of any such litigation to which a premier certified lender is a party), and liquidate loans'';

(5) in subsection (f), by striking ''State or local'' and inserting ''certified'';

(6) in subsection (g), by striking the subsection heading and inserting the following:

''(g) EFFECT OF SUSPENSION OR REVOCATION.—'';

(7) by striking subsection (h) and inserting the following:

''(h) PROGRAM GOALS.—Each certified development company participating in the program under this section shall establish a goal of processing a minimum of not less than 50 percent of the loan applications for assistance under section 504 pursuant to the program authorized under this section.''; and

(8) in subsection (i), by striking ''other lenders'' and inserting ''other lenders, specifically comparing default rates and recovery rates on liquidations''.

(b) REGULATIONS.—The Administrator shall—

(1) not later than 150 days after the date of enactment of this Act, promulgate regulations to carry out the amendments made by subsection (a); and

(2) not later than 180 days after the date of enactment of this Act, issue program guidelines and fully implement the amendments made by subsection (a).

(c) PROGRAM EXTENSION.—Section 217(b) of the Small Business Reauthorization and Amendments Act of 1994 (15 U.S.C. 697e note) is amended by striking ''October 1, 1997'' and inserting ''October 1, 2000''.

Subtitle D—Miscellaneous Provisions

SEC. 231. BACKGROUND CHECK OF LOAN APPLICANTS.

Section 7(a) of the Small Business Act (15 U.S.C. 636(a)) is amended—

(1) by striking ''(a) The Administration'' and inserting the following:

''(a) LOANS TO SMALL BUSINESS CONCERNS; ALLOWABLE PURPOSES; QUALIFIED BUSINESS; RESTRICTIONS AND LIMITATIONS.—The Administration''; and

(2) in paragraph (1)—

(A) by striking ''(1) No financial'' and inserting the following:

''(1) IN GENERAL.—

''(A) CREDIT ELSEWHERE.—No financial''; and

(B) by adding at the end the following:

''(B) BACKGROUND CHECKS.—Prior to the approval of any loan made pursuant to this subsection, or section 503 of the Small Business Investment Act of 1958, the Administrator may verify the applicant's criminal background, or lack thereof, through the best available means, including, if possible, use of the National Crime Information Center computer system at the Federal Bureau of Investigation.''.

SEC. 232. REPORT ON INCREASED LENDER APPROVAL, SERVICING, FORECLOSURE, LIQUIDATION, AND LITIGATION OF SECTION 7(a) LOANS.

(a) IN GENERAL.—

(1) SUBMISSION.—Not later than 6 months after the date of enactment of this Act, the Administrator shall submit to the Committees a report on action taken and planned for future reliance on private sector lender resources to originate, approve, close, service, liquidate, foreclose, and litigate loans made under section 7(a) of the Small Business Act.

(2) CONTENTS.—The report under this subsection shall address administrative and other steps necessary to achieve the results described in paragraph (1), including—

(A) streamlining the process for approving lenders and standardizing requirements;

(B) establishing uniform reporting requirements using on-line automated capabilities to the maximum extent feasible;

(C) reducing paperwork through automation, simplified forms, or incorporation of lender's forms;

(D) providing uniform standards for approval, closing, servicing, foreclosure, and liquidation;

(E) promulgating new regulations or amending existing ones;

(F) establishing a timetable for implementing the plan for reliance on private sector lenders;

(G) implementing organizational changes at SBA; and

(H) estimating the annual savings that would occur as a result of implementation.

(b) CONSULTATION.—In preparing the report under subsection (a), the Administrator shall consult with, among others—

(1) borrowers and lenders under section 7(a) of the Small Business Act;

(2) small businesses that are potential program participants under section 7(a) of the Small Business Act;

(3) financial institutions that are potential program lenders under section 7(a) of the Small Business Act; and

(4) representative industry associations.

SEC. 233. COMPLETION OF PLANNING FOR LOAN MONITORING SYSTEM.

(a) IN GENERAL.—The Administrator shall perform and complete the planning needed to serve as the basis for funding the development and implementation of the computerized loan monitoring system, including—

(1) fully defining the system requirement using on-line, automated capabilities to the extent feasible;

(2) identifying all data inputs and outputs necessary for timely report generation;

(3) benchmark loan monitoring business processes and systems against comparable industry processes and, if appropriate, simplify or redefine work processes based on these benchmarks;

(4) determine data quality standards and control systems for ensuring information accuracy;

(5) identify an acquisition strategy and work increments to completion;

(6) analyze the benefits and costs of alternatives and use to demonstrate the advantage of the final project;

(7) ensure that the proposed information system is consistent with the agency's information architecture; and

(8) estimate the cost to system completion, identifying the essential cost element.

(b) REPORT.—

(1) IN GENERAL.—On the date that is 6 months after the date of enactment of this Act, the Administrator shall submit a report on the progress of the Administrator in carrying out subsection (a) to—

(A) the Committees; and

(B) the Comptroller General of the United States.

(2) EVALUATION.—Not later than 28 days after receipt of the report under paragraph (1)(B), the Comptroller General of the United States shall—

(A) prepare a written evaluation of the report for compliance with subsection (a); and

(B) submit the evaluation to the Committees.

(3) LIMITATION.—None of the funds provided for the purchase of the loan monitoring system may be obligated or expended until 45 days after the date on which the Committees and the Comptroller General of the United States receive the report under paragraph (1).

TITLE III—WOMEN'S BUSINESS ENTERPRISES

SEC. 301. INTERAGENCY COMMITTEE PARTICIPATION.

Section 403 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended—

(1) in subsection (a)(2)(A)—

(A) by striking ''and Amendments Act of 1994'' and inserting ''Act of 1997''; and

(B) by inserting before the final period '', and who shall report directly to the head of the agency on the status of the activities of the Interagency Committee'';

(2) in subsection (a)(2)(B), by inserting before the final period the following: ''and shall report directly to the Administrator on the status of the activities on the Interagency Committee and shall serve as the Interagency Committee Liaison to the National Women's Business Council established under section 405''; and

(3) in subsection (b), by striking ''and Amendments Act of 1994'' and inserting ''Act of 1997''.

SEC. 302. REPORTS.

Section 404 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended—

(1) by inserting '', through the Small Business Administration,'' after ''transmit'';

(2) by striking paragraph (1) and redesignating paragraphs (2) through (4) as paragraphs (1) through (3), respectively; and

(3) in paragraph (1), as redesignated, by inserting before the semicolon the following: '', including a verbatim report on the status of progress of the Interagency Committee in meeting its responsibilities and duties under section 402(a)''.

SEC. 303. COUNCIL DUTIES.

Section 406 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended—

(1) in subsection (c), by inserting after ''Administrator'' the following: ''(through the Assistant Administrator of the Office of Women's Business Ownership)''; and

(2) in subsection (d)—

(A) in paragraph (4), by striking ''and'' at the end;

(B) in paragraph (5), by striking the period at the end and inserting a semicolon; and

(C) by adding at the end the following:

''(6) not later than 90 days after the last day of each fiscal year, submit to the President and to the Committee on Small Business of the Senate and the Committee on Small Business of the House of Representatives, a report containing—

''(A) a detailed description of the activities of the council, including a status report on the Council's progress toward meeting its duties outlined in subsections (a) and (d) of section 406;

''(B) the findings, conclusions, and recommendations of the Council; and

''(C) the Council's recommendations for such legislation and administrative actions as the Council considers appropriate to promote the development of small business concerns owned and controlled by women.

''(e) FORM OF TRANSMITTAL.—The information included in each report under subsection (d) that is described in subparagraphs (A) through (C) of subsection (d)(6), shall be reported verbatim, together with any separate additional, concurring, or dissenting views of the Administrator.''.

SEC. 304. COUNCIL MEMBERSHIP.

Section 407 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended—

(1) in subsection (a), by striking ''and Amendments Act of 1994'' and inserting ''Act of 1997'';

(2) in subsection (b)—

(A) by striking ''and Amendments Act of 1994'' and inserting ''Act of 1997'';

(B) by inserting after ''the Administrator shall'' the following: '', after receiving the recommendations of the Chairman and the Ranking Member of the Committees on Small Business of the House of Representatives and the Senate,'';

(C) by striking ''9'' and inserting ''14'';

(D) in paragraph (1), by striking ''2'' and inserting ''4'';

(E) in paragraph (2), by striking ''2'' and inserting ''4''; and

(F) in paragraph (3)—

(i) by striking ''5'' and inserting ''6'';

(ii) by striking ''national''; and

(iii) by inserting '', including representatives of women's business center sites'' before the period at the end;

(3) in subsection (c), by inserting ''(including both urban and rural areas)'' after ''geographic'';

(4) by striking subsection (d) and inserting the following:

''(d) TERMS.—Each member of the Council shall be appointed for a term of 3 years, except that, of the initial members appointed to the Council—

''(1) 2 members appointed under subsection (b)(1) shall be appointed for a term of 1 year;

''(2) 2 members appointed under subsection (b)(2) shall be appointed for a term of 1 year; and

''(3) each member appointed under subsection (b)(3) shall be appointed for a term of 2 years.''; and

(5) by striking subsection (f) and inserting the following:

''(f) VACANCIES.—

''(1) IN GENERAL.—A vacancy on the Council shall be filled not later than 30 days after the date on which the vacancy occurs, in the manner in which the original appointment was made, and shall be subject to any conditions that applied to the original appointment.

''(2) UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.''.

SEC. 305. AUTHORIZATION OF APPROPRIATIONS.

Section 409 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended to read as follows:

''SEC. 411. AUTHORIZATION OF APPROPRIATIONS.

''(a) IN GENERAL.—There is authorized to be appropriated to carry out this title $600,000, for each of fiscal years 1998 through 2000, of which $200,000 shall be available in each fiscal year to carry out sections 409 and 410.

''(b) BUDGET REVIEW.—No amount made available under this section for any fiscal year may be obligated or expended by the Council before the date on which the Council reviews and approves the operating budget of the Council to carry out the responsibilities of the Council for that fiscal year.''.

SEC. 306. NATIONAL WOMEN'S BUSINESS COUNCIL PROCUREMENT PROJECT.

The Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended by inserting after section 408 the following:

''SEC. 409. NATIONAL WOMEN'S BUSINESS COUNCIL PROCUREMENT PROJECT.

''(a) FEDERAL PROCUREMENT STUDY.—

''(1) IN GENERAL.—During the first fiscal year for which amounts are made available to carry out this section, the Council shall conduct a study on the award of Federal prime contracts and subcontracts to women-owned businesses, which study shall include—

''(A) an analysis of data collected by Federal agencies on contract awards to women-owned businesses;

''(B) a determination of the degree to which individual Federal agencies are in compliance with the 5 percent women-owned business procurement goal established by section 15(g)(1) of the Small Business Act (15 U.S.C. 644(g)(1));

''(C) a determination of the types and amounts of Federal contracts characteristically awarded to women-owned businesses; and

''(D) other relevant information relating to participation of women-owned businesses in Federal procurement.

''(2) SUBMISSION OF RESULTS.—Not later than 12 months after initiating the study under paragraph (1), the Council shall submit to the Committees on Small Business of the House of Representatives and the Senate, and to the President, the results of the study conducted under paragraph (1).

''(b) BEST PRACTICES REPORT.—Not later than 18 months after initiating the study under subsection (a)(1), the Council shall submit to the Committees on Small Business of the House of Representatives and the Senate, and to the President, a report, which shall include—

''(1) an analysis of the most successful practices in attracting women-owned businesses as prime contractors and subcontractors by—

''(A) Federal agencies (as supported by findings from the study required under subsection (a)(1)) in Federal procurement awards; and

''(B) the private sector; and

''(2) recommendations for policy changes in Federal procurement practices, including an increase in the Federal procurement goal for women-owned businesses, in order to maximize the number of women-owned businesses performing Federal contracts.

''(c) CONTRACT AUTHORITY.—In conducting any study or other research under this section, the Council may contract with 1 or more public or private entities.''.

SEC. 307. STUDIES AND OTHER RESEARCH.

The Women's Business Ownership Act of 1988 (15 U.S.C. 631 note) is amended by inserting after section 409 (as added by section 306 of this title) the following:

''SEC. 410. STUDIES AND OTHER RESEARCH.

''(a) IN GENERAL.—To the extent that it does not delay submission of the report under section 409(b), the Council may also conduct such studies and other research relating to the award of Federal prime contracts and subcontracts to women-owned businesses, or to issues relating to access to credit and investment capital by women entrepreneurs, as the Council determines to be appropriate.

''(b) CONTRACT AUTHORITY.—In conducting any study or other research under this section, the Council may contract with 1 or more public or private entities.''.

SEC. 308. WOMEN'S BUSINESS CENTERS.

(a) IN GENERAL.—Section 29 of the Small Business Act (15 U.S.C. 656) is amended to read as follows:

''SEC. 29. WOMEN'S BUSINESS CENTER PROGRAM.

''(a) DEFINITIONS.—In this section—

''(1) the term 'Assistant Administrator' means the Assistant Administrator of the Office of Women's Business Ownership established under subsection (g);

''(2) the term 'small business concern owned and controlled by women', either startup or existing, includes any small business concern—

''(A) that is not less than 51 percent owned by 1 or more women; and

''(B) the management and daily business operations of which are controlled by 1 or more women; and

''(3) the term 'women's business center site' means the location of—

''(A) a women's business center; or

''(B) 1 or more women's business centers, established in conjunction with another women's business center in another location within a State or region—

''(i) that reach a distinct population that would otherwise not be served;

''(ii) whose services are targeted to women; and

''(iii) whose scope, function, and activities are similar to those of the primary women's business center or centers in conjunction with which it was established.

''(b) AUTHORITY.—The Administration may provide financial assistance to private organizations to conduct 5-year projects for the benefit of small business concerns owned and controlled by women. The projects shall provide—

''(1) financial assistance, including training and counseling in how to apply for and secure business credit and investment capital, preparing and presenting financial statements, and managing cash flow and other financial operations of a business concern;

''(2) management assistance, including training and counseling in how to plan, organize, staff, direct, and control each major activity and function of a small business concern; and

''(3) marketing assistance, including training and counseling in identifying and segmenting domestic and international market opportunities, preparing and executing marketing plans, developing pricing strategies, locating contract opportunities, negotiating contracts, and utilizing varying public relations and advertising techniques.

''(c) CONDITIONS OF PARTICIPATION.—

''(1) NON-FEDERAL CONTRIBUTIONS.—As a condition of receiving financial assistance authorized by this section, the recipient organization shall agree to obtain, after its application has been approved and notice of award has been issued, cash contributions from non-Federal sources as follows:

''(A) in the first and second years, 1 non-Federal dollar for each 2 Federal dollars;

''(B) in the third and fourth years, 1 non-Federal dollar for each Federal dollar; and

''(C) in the fifth year, 2 non-Federal dollars for each Federal dollar.

''(2) FORM OF NON-FEDERAL CONTRIBUTIONS.—Not more than one-half of the non-Federal sector matching assistance may be in the form of in-kind contributions that are budget line items only, including office equipment and office space.

''(3) FORM OF FEDERAL CONTRIBUTIONS.—The financial assistance authorized pursuant to this section may be made by grant, contract, or cooperative agreement and may contain such provision, as necessary, to provide for payments in lump sum or installments, and in advance or by way of reimbursement. The Administration may disburse up to 25 percent of each year's Federal share awarded to a recipient organization after notice of the award has been issued and before the non-Federal sector matching funds are obtained.

''(4) FAILURE TO OBTAIN NON-FEDERAL FUNDING.—If any recipient of assistance fails to obtain the required non-Federal contribution during any project, it shall not be eligible thereafter for advance disbursements pursuant to paragraph (3) during the remainder of that project, or for any other project for which it is or may be funded by the Administration, and prior to approving assistance to such organization for any other projects, the Administration shall specifically determine whether the Administration believes that the recipient will be able to obtain the requisite non-Federal funding and enter a written finding setting forth the reasons for making such determination.

''(d) CONTRACT AUTHORITY.—A women's business center may enter into a contract with a Federal department or agency to provide specific assistance to women and other underserved small business concerns. Performance of such contract should not hinder the women's business centers in carrying out the terms of the grant received by the women's business centers from the Administration.

''(e) SUBMISSION OF 5-YEAR PLAN.—Each applicant organization initially shall submit a 5-year plan to the Administration on proposed fundraising and training activities, and a recipient organization may receive financial assistance under this program for a

maximum of 5 years per women's business center site.

''(f) CRITERIA.—The Administration shall evaluate and rank applicants in accordance with predetermined selection criteria that shall be stated in terms of relative importance. Such criteria and their relative importance shall be made publicly available and stated in each solicitation for applications made by the Administration. The criteria shall include—

''(1) the experience of the applicant in conducting programs or ongoing efforts designed to impart or upgrade the business skills of women business owners or potential owners;

''(2) the present ability of the applicant to commence a project within a minimum amount of time;

''(3) the ability of the applicant to provide training and services to a representative number of women who are both socially and economically disadvantaged; and

''(4) the location for the women's business center site proposed by the applicant.

''(g) OFFICE OF WOMEN'S BUSINESS OWNERSHIP.—

''(1) ESTABLISHMENT.—There is established within the Administration an Office of Women's Business Ownership, which shall be responsible for the administration of the Administration's programs for the development of women's business enterprises (as defined in section 408 of the Women's Business Ownership Act of 1988 (15 U.S.C. 631 note)). The Office of Women's Business Ownership shall be administered by an Assistant Administrator, who shall be appointed by the Administrator.

''(2) ASSISTANT ADMINISTRATOR OF THE OFFICE OF WOMEN'S BUSINESS OWNERSHIP.—

''(A) QUALIFICATION.—The position of Assistant Administrator shall be a Senior Executive Service position under section 3132(a)(2) of title 5, United States Code. The Assistant Administrator shall serve as a noncareer appointee (as defined in section 3132(a)(7) of that title).

''(B) RESPONSIBILITIES AND DUTIES.—

''(i) RESPONSIBILITIES.—The responsibilities of the Assistant Administrator shall be to administer the programs and services of the Office of Women's Business Ownership established to assist women entrepreneurs in the areas of—

''(I) starting and operating a small business;

''(II) development of management and technical skills;

''(III) seeking Federal procurement opportunities; and

''(IV) increasing the opportunity for access to capital.

''(ii) DUTIES.—The Assistant Administrator shall—

''(I) administer and manage the Women's Business Center program;

''(II) recommend the annual administrative and program budgets for the Office of Women's Business Ownership (including the budget for the Women's Business Center program);

''(III) establish appropriate funding levels therefore;

''(IV) review the annual budgets submitted by each applicant for the Women's Business Center program;

''(V) select applicants to participate in the program under this section;

''(VI) implement this section;

''(VII) maintain a clearinghouse to provide for the dissemination and exchange of information between women's business centers;

''(VIII) serve as the vice chairperson of the Interagency Committee on Women's Business Enterprise;

''(IX) serve as liaison for the National Women's Business Council; and

''(X) advise the Administrator on appointments to the Women's Business Council.

''(C) CONSULTATION REQUIREMENTS.—In carrying out the responsibilities and duties described in this paragraph, the Assistant Administrator shall confer with and seek the advice of the Administration officials in areas served by the women's business centers.

''(h) PROGRAM EXAMINATION.—

''(1) IN GENERAL.—Not later than 180 days after the date of enactment of the Small Business Reauthorization Act of 1997, the Administrator shall develop and implement an annual programmatic and financial examination of each women's business center established pursuant to this section.

''(2) EXTENSION OF CONTRACTS.—In extending or renewing a contract with a women's business center, the Administrator shall consider the results of the examination conducted under paragraph (1).

''(i) CONTRACT AUTHORITY.—The authority of the Administrator to enter into contracts shall be in effect for each fiscal year only to the extent and in the amounts as are provided in advance in appropriations Acts. After the Administrator has entered into a contract, either as a grant or a cooperative agreement, with any applicant under this section, it shall not suspend, terminate, or fail to renew or extend any such contract unless the Administrator provides the applicant with written notification setting forth the reasons therefore and affords the applicant an opportunity for a hearing, appeal, or other administrative proceeding under chapter 5 of title 5, United States Code.

''(j) REPORT.—The Administrator shall prepare and submit an annual report to the Committees on Small Business of the House of Representatives and the Senate on the effectiveness of all projects conducted under the authority of this section. Such report shall provide information concerning—

''(1) the number of individuals receiving assistance;

''(2) the number of startup business concerns formed;

''(3) the gross receipts of assisted concerns;

''(4) increases or decreases in profits of assisted concerns; and

''(5) the employment increases or decreases of assisted concerns.

''(k) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated $8,000,000 for each fiscal year to carry out the projects authorized under this section, of which, for fiscal year 1998, not more than 5 percent may be used for administrative expenses related to the program under this section.

''(2) USE OF AMOUNTS.—Amounts made available under this subsection for fiscal year 1999, and each fiscal year thereafter, may only be used for grant awards and may not be used for costs incurred by the Administration in connection with the management and administration of the program under this section.

''(3) EXPEDITED ACQUISITION.—Notwithstanding any other provision of law, the Administrator, acting through the Assistant Administrator, may use such expedited acquisition methods as the Administrator determines to be appropriate to carry out this section, except that the Administrator shall ensure that all small business sources are provided a reasonable opportunity to submit proposals.''.

(b) APPLICABILITY.—

(1) IN GENERAL.—Subject to paragraph (2), any organization conducting a 3-year project under section 29 of the Small Business Act (15 U.S.C. 656) (as in effect on the day before the effective date of this Act) on September 30, 1997, may request an extension of the term of that project to a total term of 5 years. If such an extension is made, the organization shall receive financial assistance in accordance with section 29(c) of the Small Business Act (as amended by this section) subject to procedures established by the Administrator, in coordination with the Assistant Administrator of the Office of Women's Business Ownership established under section 29 of the Small Business Act (15 U.S.C. 656) (as amended by this section).

(2) TERMS OF ASSISTANCE FOR CERTAIN ORGANIZATIONS.—Any organization operating in the third year of a 3-year project under section 29 of the Small Business Act (15 U.S.C. 656) (as in effect on the day before the effective date of this Act) on September 30, 1997, may request an extension of the term of that project to a total term of 5 years. If such an extension is made, during the fourth and fifth years of the project, the organization shall receive financial assistance in accordance with section 29(c)(1)(C) of the Small Business Act (as amended by this section) subject to procedures established by the Administrator, in coordination with the Assistant Administrator of the Office of Women's Business Ownership established under section 29 of the Small Business Act (15 U.S.C. 656) (as amended by this section).

TITLE IV—COMPETITIVENESS PROGRAM AND PROCUREMENT OPPORTUNITIES

Subtitle A—Small Business Competitiveness Program

SEC. 401. PROGRAM TERM.

Section 711(c) of the Small Business Competitiveness Demonstration Program Act of 1988 (15 U.S.C. 644 note) is amended by striking '', and terminate on September 30, 1997''.

SEC. 402. MONITORING AGENCY PERFORMANCE.

Section 712(d)(1) of the Small Business Competitiveness Demonstration Program Act of 1988 (15 U.S.C. 644 note) is amended to read as follows:

''(1) Participating agencies shall monitor the attainment of their small business participation goals on an annual basis. An annual review by each participating agency shall be completed not later than January 31 of each year, based on the data for the preceding fiscal year, from October 1 through September 30.''.

SEC. 403. REPORTS TO CONGRESS.

Section 716(a) of the Small Business Competitiveness Demonstration Program Act of 1988 (15 U.S.C. 644 note) is amended—

(1) by striking ''1996'' and inserting ''2000'';

(2) by striking ''for Federal Procurement Policy'' and inserting ''of the Small Business Administration''; and

(3) by striking ''Government Operations'' and inserting ''Government Reform and Oversight''.

SEC. 404. SMALL BUSINESS PARTICIPATION IN DREDGING.

Section 722(a) of the Small Business Competitiveness Demonstration Program Act of 1988 (15 U.S.C. 644 note) is amended by striking ''and terminating on September 30, 1997''.

SEC. 405. TECHNICAL AMENDMENTS.

Section 717 of the Small Business Competitiveness Demonstration Program Act of 1988 (15 U.S.C. 644 note) is amended—

(1) by inserting ''or North American Industrial Classification Code'' after ''standard industrial classification code'' each place it appears; and

(2) by inserting ''or North American Industrial Classification Codes'' after ''standard industrial classification codes'' each place it appears.

Subtitle B—Small Business Procurement Opportunities Program

SEC. 411. CONTRACT BUNDLING.

Section 2 of the Small Business Act (15 U.S.C. 631) is amended by adding at the end the following:

''(j) CONTRACT BUNDLING.—In complying with the statement of congressional policy expressed in subsection (a), relating to fos-

tering the participation of small business concerns in the contracting opportunities of the Government, each Federal agency, to the maximum extent practicable, shall—

''(1) comply with congressional intent to foster the participation of small business concerns as prime contractors, subcontractors, and suppliers;

''(2) structure its contracting requirements to facilitate competition by and among small business concerns, taking all reasonable steps to eliminate obstacles to their participation; and

''(3) avoid unnecessary and unjustified bundling of contract requirements that precludes small business participation in procurements as prime contractors.''.

SEC. 412. DEFINITION OF CONTRACT BUNDLING.

Section 3 of the Small Business Act (15 U.S.C. 632) is amended by adding at the end the following:

''(o) DEFINITIONS OF BUNDLING OF CONTRACT REQUIREMENTS AND RELATED TERMS.—In this Act:

''(1) BUNDLED CONTRACT.—The term 'bundled contract' means a contract that is entered into to meet requirements that are consolidated in a bundling of contract requirements.

''(2) BUNDLING OF CONTRACT REQUIREMENTS.—The term 'bundling of contract requirements' means consolidating 2 or more procurement requirements for goods or services previously provided or performed under separate smaller contracts into a solicitation of offers for a single contract that is likely to be unsuitable for award to a small-business concern due to—

''(A) the diversity, size, or specialized nature of the elements of the performance specified;

''(B) the aggregate dollar value of the anticipated award;

''(C) the geographical dispersion of the contract performance sites; or

''(D) any combination of the factors described in subparagraphs (A), (B), and (C).

''(3) SEPARATE SMALLER CONTRACT.—The term 'separate smaller contract', with respect to a bundling of contract requirements, means a contract that has been performed by 1 or more small business concerns or was suitable for award to 1 or more small business concerns.''.

SEC. 413. ASSESSING PROPOSED CONTRACT BUNDLING.

(a) IN GENERAL.—Section 15 of the Small Business Act (15 U.S.C. 644) is amended by inserting after subsection (d) the following:

''(e) PROCUREMENT STRATEGIES; CONTRACT BUNDLING.—

''(1) IN GENERAL.—To the maximum extent practicable, procurement strategies used by the various agencies having contracting authority shall facilitate the maximum participation of small business concerns as prime contractors, subcontractors, and suppliers.

''(2) MARKET RESEARCH.—

''(A) IN GENERAL.—Before proceeding with an acquisition strategy that could lead to a contract containing consolidated procurement requirements, the head of an agency shall conduct market research to determine whether consolidation of the requirements is necessary and justified.

''(B) FACTORS.—For purposes of subparagraph (A), consolidation of the requirements may be determined as being necessary and justified if, as compared to the benefits that would be derived from contracting to meet those requirements if not consolidated, the Federal Government would derive from the consolidation measurably substantial benefits, including any combination of benefits that, in combination, are measurably substantial. Benefits described in the preceding sentence may include the following:

''(i) Cost savings.

''(ii) Quality improvements.

''(iii) Reduction in acquisition cycle times.

''(iv) Better terms and conditions.

''(v) Any other benefits.

''(C) REDUCTION OF COSTS NOT DETERMINATIVE.—The reduction of administrative or personnel costs alone shall not be a justification for bundling of contract requirements unless the cost savings are expected to be substantial in relation to the dollar value of the procurement requirements to be consolidated.

''(3) STRATEGY SPECIFICATIONS.—If the head of a contracting agency determines that a proposed procurement strategy for a procurement involves a substantial bundling of contract requirements, the proposed procurement strategy shall—

''(A) identify specifically the benefits anticipated to be derived from the bundling of contract requirements;

''(B) set forth an assessment of the specific impediments to participation by small business concerns as prime contractors that result from the bundling of contract requirements and specify actions designed to maximize small business participation as subcontractors (including suppliers) at various tiers under the contract or contracts that are awarded to meet the requirements; and

''(C) include a specific determination that the anticipated benefits of the proposed bundled contract justify its use.

''(4) CONTRACT TEAMING.—In the case of a solicitation of offers for a bundled contract that is issued by the head of an agency, a small-business concern may submit an offer that provides for use of a particular team of subcontractors for the performance of the contract. The head of the agency shall evaluate the offer in the same manner as other offers, with due consideration to the capabilities of all of the proposed subcontractors. If a small business concern teams under this paragraph, it shall not affect its status as a small business concern for any other purpose.''.

(b) ADMINISTRATION REVIEW.—Section 15(a) of the Small Business Act (15 U.S.C. 644(a)) is amended in the third sentence—

(1) by inserting ''or the solicitation involves an unnecessary or unjustified bundling of contract requirements, as determined by the Administration,'' after ''discrete construction projects,'';

(2) by striking ''or (4)'' and inserting ''(4)''; and

(3) by inserting before the period at the end of the sentence the following: '', or (5) why the agency has determined that the bundled contract (as defined in section 3(o)) is necessary and justified''.

(c) RESPONSIBILITIES OF AGENCY SMALL BUSINESS ADVOCATES.—Section 15(k) of the Small Business Act (15 U.S.C. 644(k)) is amended—

(1) by redesignating paragraphs (5) through (9) as paragraphs (6) through (10), respectively; and

(2) by inserting after paragraph (4) the following:

''(5) identify proposed solicitations that involve significant bundling of contract requirements, and work with the agency acquisition officials and the Administration to revise the procurement strategies for such proposed solicitations where appropriate to increase the probability of participation by small businesses as prime contractors, or to facilitate small business participation as subcontractors and suppliers, if a solicitation for a bundled contract is to be issued;''.

SEC. 414. REPORTING OF BUNDLED CONTRACT OPPORTUNITIES.

(a) DATA COLLECTION REQUIRED.—The Federal Procurement Data System described in section 6(d)(4)(A) of the Office of Federal Procurement Policy Act (41 U.S.C. 405(d)(4)(A)) shall be modified to collect data regarding bundling of contract requirements when the contracting officer anticipates that the resulting contract price, including all options, is expected to exceed $5,000,000. The data shall reflect a determination made by the contracting officer regarding whether a particular solicitation constitutes a contract bundling.

(b) DEFINITIONS.—In this section, the term ''bundling of contract requirements'' has the meaning given that term in section 3(o) of the Small Business Act (15 U.S.C. 632(o)) (as added by section 412 of this subtitle).

SEC. 415. EVALUATING SUBCONTRACT PARTICIPATION IN AWARDING CONTRACTS.

Section 8(d)(4) of the Small Business Act (15 U.S.C. 637(d)(4)) is amended by adding at the end the following:

''(G) The following factors shall be designated by the Federal agency as significant factors for purposes of evaluating offers for a bundled contract where the head of the agency determines that the contract offers a significant opportunity for subcontracting:

''(i) A factor that is based on the rate provided under the subcontracting plan for small business participation in the performance of the contract.

''(ii) For the evaluation of past performance of an offeror, a factor that is based on the extent to which the offeror attained applicable goals for small business participation in the performance of contracts.''.

SEC. 416. IMPROVED NOTICE OF SUBCONTRACTING OPPORTUNITIES.

(a) USE OF THE COMMERCE BUSINESS DAILY AUTHORIZED.—Section 8 of the Small Business Act (15 U.S.C. 637) is amended by adding at the end the following:

''(k) NOTICES OF SUBCONTRACTING OPPORTUNITIES.—

''(1) IN GENERAL.—Notices of subcontracting opportunities may be submitted for publication in the Commerce Business Daily by—

''(A) a business concern awarded a contract by an executive agency subject to subsection (e)(1)(C); and

''(B) a business concern that is a subcontractor or supplier (at any tier) to such contractor having a subcontracting opportunity in excess of $10,000.

''(2) CONTENT OF NOTICE.—The notice of a subcontracting opportunity shall include—

''(A) a description of the business opportunity that is comparable to the description specified in paragraphs (1), (2), (3), and (4) of subsection (f); and

''(B) the due date for receipt of offers.''.

(b) REGULATIONS REQUIRED.—The Federal Acquisition Regulation shall be amended to provide uniform implementation of the amendments made by this section.

(c) CONFORMING AMENDMENT.—Section 8(e)(1)(C) of the Small Business Act (15 U.S.C. 637(e)(1)(C)) is amended by striking ''$25,000'' each place that term appears and inserting ''$100,000''.

SEC. 417. DEADLINES FOR ISSUANCE OF REGULATIONS.

(a) PROPOSED REGULATIONS.—Proposed amendments to the Federal Acquisition Regulation or proposed Small Business Administration regulations under this subtitle and the amendments made by this subtitle shall be published not later than 120 days after the date of enactment of this Act for the purpose of obtaining public comment pursuant to section 22 of the Office of Federal Procurement Policy Act (41 U.S.C. 418b), or chapter 5 of title 5, United States Code, as appropriate. The public shall be afforded not less than 60 days to submit comments.

(b) FINAL REGULATIONS.—Final regulations shall be published not later than 270 days after the date of enactment of this Act. The

effective date for such final regulations shall be not less than 30 days after the date of publication.

TITLE V—MISCELLANEOUS PROVISIONS

SEC. 501. SMALL BUSINESS TECHNOLOGY TRANSFER PROGRAM.

(a) REQUIRED EXPENDITURES.—Section 9(n) of the Small Business Act (15 U.S.C. 638(n)) is amended by striking paragraph (1) and inserting the following:

''(1) REQUIRED EXPENDITURE AMOUNTS.—With respect to fiscal years 1998, 1999, 2000, and 2001, each Federal agency that has an extramural budget for research, or research and development, in excess of $1,000,000,000 for that fiscal year, is authorized to expend with small business concerns not less than 0.15 percent of that extramural budget specifically in connection with STTR programs that meet the requirements of this section and any policy directives and regulations issued under this section.''.

(b) REPORTS AND OUTREACH.—

(1) IN GENERAL.—Section 9 of the Small Business Act (15 U.S.C. 638) is amended—

(A) in subsection (o)—

(i) by redesignating paragraphs (8) through (11) as paragraphs (10) through (13), respectively; and

(ii) by inserting after paragraph (7) the following:

''(8) include, as part of its annual performance plan as required by subsections (a) and (b) of section 1115 of title 31, United States Code, a section on its STTR program, and shall submit such section to the Committee on Small Business of the Senate, and the Committee on Science and the Committee on Small Business of the House of Representatives;

''(9) collect such data from awardees as is necessary to assess STTR program outputs and outcomes;'';

(B) in subsection (e)(4)(A), by striking ''(ii)''; and

(C) by adding at the end the following:

''(s) OUTREACH.—

''(1) DEFINITION OF ELIGIBLE STATE.—In this subsection, the term 'eligible State' means a State—

''(A) if the total value of contracts awarded to the State during fiscal year 1995 under this section was less than $5,000,000; and

''(B) that certifies to the Administration described in paragraph (2) that the State will, upon receipt of assistance under this subsection, provide matching funds from non-Federal sources in an amount that is not less than 50 percent of the amount provided under this subsection.

''(2) PROGRAM AUTHORITY.—Of amounts made available to carry out this section for fiscal year 1998, 1999, 2000, or 2001 the Administrator may expend with eligible States not more than $2,000,000 in each such fiscal year in order to increase the participation of small business concerns located in those States in the programs under this section.

''(3) AMOUNT OF ASSISTANCE.—The amount of assistance provided to an eligible State under this subsection in any fiscal year—

''(A) shall be equal to twice the total amount of matching funds from non-Federal sources provided by the State; and

''(B) shall not exceed $100,000.

''(4) USE OF ASSISTANCE.—Assistance provided to an eligible State under this subsection shall be used by the State, in consultation with State and local departments and agencies, for programs and activities to increase the participation of small business concerns located in the State in the programs under this section, including—

''(A) the establishment of quantifiable performance goals, including goals relating to—

''(i) the number of program awards under this section made to small business concerns in the State; and

''(ii) the total amount of Federal research and development contracts awarded to small business concerns in the State;

''(B) the provision of competition outreach support to small business concerns in the State that are involved in research and development; and

''(C) the development and dissemination of educational and promotional information relating to the programs under this section to small business concerns in the State.

''(t) INCLUSION IN STRATEGIC PLANS.—Program information relating to the SBIR and STTR programs shall be included by each Federal agency in any update or revision required of the Federal agency under section 306(b) of title 5, United States Code.''.

(2) REPEAL.—Effective October 1, 2001, section 9(s) of the Small Business Act (as added by paragraph (1) of this subsection) is repealed.

SEC. 502. SMALL BUSINESS DEVELOPMENT CENTERS.

(a) IN GENERAL.—Section 21(a) of the Small Business Act (15 U.S.C. 648(a)) is amended—

(1) in paragraph (1)—

(A) by inserting ''any women's business center operating pursuant to section 29,'' after ''credit or finance corporation,'';

(B) by inserting ''or a women's business center operating pursuant to section 29'' after ''other than an institution of higher education''; and

(C) by inserting ''and women's business centers operating pursuant to section 29'' after ''utilize institutions of higher education'';

(2) in paragraph (3)—

(A) by striking '', but with'' and all that follows through ''parties.'' and inserting the following: ''for the delivery of programs and services to the small business community. Such programs and services shall be jointly developed, negotiated, and agreed upon, with full participation of both parties, pursuant to an executed cooperative agreement between the Small Business Development Center applicant and the Administration.''; and

(B) by adding at the end the following:

''(C) On an annual basis, the Small Business Development Center shall review and coordinate public and private partnerships and cosponsorships with the Administration for the purpose of more efficiently leveraging available resources on a National and a State basis.'';

(3) in paragraph (4)(C)—

(A) by striking clause (i) and inserting the following:

''(i) IN GENERAL.—

''(I) GRANT AMOUNT.—Subject to subclauses (II) and (III), the amount of a grant received by a State under this section shall be equal to the greater of $500,000, or the sum of—

''(aa) the State's pro rata share of the national program, based upon the population of the State as compared to the total population of the United States; and

''(bb) $300,000 in fiscal year 1998, $400,000 in fiscal year 1999, and $500,000 in each fiscal year thereafter.

''(II) PRO RATA REDUCTIONS.—If the amount made available to carry out this section for any fiscal year is insufficient to carry out subclause (I)(bb), the Administration shall make pro rata reductions in the amounts otherwise payable to States under subclause (I)(bb).

''(III) MATCHING REQUIREMENT.—The amount of a grant received by a State under this section shall not exceed the amount of matching funds from sources other than the Federal Government provided by the State under subparagraph (A).''; and

(B) in clause (iii), by striking ''(iii)'' and all that follows through ''1997.'' and inserting the following:

''(iii) NATIONAL PROGRAM.—There are authorized to be appropriated to carry out the national program under this section—

''(I) $85,000,000 for fiscal year 1998;

''(II) $90,000,000 for fiscal year 1999; and

''(III) $95,000,000 for fiscal year 2000 and each fiscal year thereafter.''; and

(4) in paragraph (6)—

(A) in subparagraph (A), by striking ''and'' at the end;

(B) in subparagraph (B), by striking the comma at the end and inserting ''; and''; and

(C) inserting after subparagraph (B) the following:

''(C) with outreach, development, and enhancement of minority-owned small business startups or expansions, HUBZone small business concerns, veteran-owned small business startups or expansions, and women-owned small business startups or expansions, in communities impacted by base closings or military or corporate downsizing, or in rural or underserved communities;''.

(b) SBDC SERVICES.—Section 21(c) of the Small Business Act (15 U.S.C. 648(c)) is amended—

(1) in paragraph (3)—

(A) in subparagraph (A), by striking ''businesses;'' and inserting ''businesses, including—

''(i) working with individuals to increase awareness of basic credit practices and credit requirements;

''(ii) working with individuals to development business plans, financial packages, credit applications, and contract proposals;

''(iii) working with the Administration to develop and provide informational tools for use in working with individuals on pre-business startup planning, existing business expansion, and export planning; and

''(iv) working with individuals referred by the local offices of the Administration and Administration participating lenders;'';

(B) in each of subparagraphs (B), (C), (D), (E), (F), (G), (M), (N), (O), (Q), and (R) by moving each margin 2 ems to the left; and

(C) in subparagraph (C), by inserting ''and the Administration'' after ''Center'';

(2) in paragraph (5)—

(A) by moving the margin 2 ems to the right;

(B) by striking ''paragraph (a)(1)'' and inserting ''subsection (a)(1)'';

(C) by striking ''which ever'' and inserting ''whichever''; and

(D) by striking ''last,,'' and inserting ''last,'';

(3) by redesignating paragraphs (4) through (7) as paragraphs (5) through (8), respectively; and

(4) in paragraph (3), in the undesignated material following subparagraph (R), by striking ''A small'' and inserting the following:

''(4) A small''.

(c) COMPETITIVE AWARDS.—Section 21(l) of the Small Business Act (15 U.S.C. 648(l)) is amended by adding at the end the following: ''If any contract or cooperative agreement under this section with an entity that is covered by this section is not renewed or extended, any award of a successor contract or cooperative agreement under this section to another entity shall be made on a competitive basis.''.

(d) PROHIBITION ON CERTAIN FEES.—Section 21 of the Small Business Act (15 U.S.C. 648) is amended by adding at the end the following:

''(m) PROHIBITION ON CERTAIN FEES.—A small business development center shall not impose or otherwise collect a fee or other compensation in connection with the provision of counseling services under this section.''.

SEC. 503. PILOT PREFERRED SURETY BOND GUARANTEE PROGRAM EXTENSION.

Section 207 of the Small Business Administration Reauthorization and Amendment Act

of 1988 (15 U.S.C. 694b note) is amended by striking ''September 30, 1997'' and inserting ''September 30, 2000''.

SEC. 504. EXTENSION OF COSPONSORSHIP AUTHORITY.

Section 401(a)(2) of the Small Business Administration Reauthorization and Amendments Act of 1994 (15 U.S.C. 637 note) is amended by striking ''September 30, 1997'' and inserting ''September 30, 2000''.

SEC. 505. ASSET SALES.

In connection with the Administration's implementation of a program to sell to the private sector loans and other assets held by the Administration, the Administration shall provide to the Committees a copy of the draft and final plans describing the sale and the anticipated benefits resulting from such sale.

SEC. 506. SMALL BUSINESS EXPORT PROMOTION.

(a) IN GENERAL.—Section 21(c)(3) of the Small Business Act (15 U.S.C. 648(c)(3)) is amended—

(1) in subparagraph (Q), by striking ''and'' at the end;

(2) in subparagraph (R), by striking the period at the end and inserting ''; and''; and

(3) by inserting after subparagraph (R) the following:

''(S) providing small business owners with access to a wide variety of export-related information by establishing on-line computer linkages between small business development centers and an international trade data information network with ties to the Export Assistance Center program.''.

(b) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out section 21(c)(3)(S) of the Small Business Act (15 U.S.C. 648(c)(3)(S)), as added by this section, $1,500,000 for each fiscal years 1998 and 1999.

SEC. 507. DEFENSE LOAN AND TECHNICAL ASSISTANCE PROGRAM.

(a) DELTA PROGRAM AUTHORIZED.—

(1) IN GENERAL.—The Administrator may administer the Defense Loan and Technical Assistance program in accordance with the authority and requirements of this section.

(2) EXPIRATION OF AUTHORITY.—The authority of the Administrator to carry out the DELTA program under paragraph (1) shall terminate when the funds referred to in subsection (g)(1) have been expended.

(3) DELTA PROGRAM DEFINED.—In this section, the terms ''Defense Loan and Technical Assistance program'' and ''DELTA program'' mean the Defense Loan and Technical Assistance program that has been established by a memorandum of understanding entered into by the Administrator and the Secretary of Defense on June 26, 1995.

(b) ASSISTANCE.—

(1) AUTHORITY.—Under the DELTA program, the Administrator may assist small business concerns that are economically dependent on defense expenditures to acquire dual-use capabilities.

(2) FORMS OF ASSISTANCE.—Forms of assistance authorized under paragraph (1) are as follows:

(A) LOAN GUARANTEES.—Loan guarantees under the terms and conditions specified under this section and other applicable law.

(B) NONFINANCIAL ASSISTANCE.—Other forms of assistance that are not financial.

(c) ADMINISTRATION OF PROGRAM.—In the administration of the DELTA program under this section, the Administrator shall—

(1) process applications for DELTA program loan guarantees;

(2) guarantee repayment of the resulting loans in accordance with this section; and

(3) take such other actions as are necessary to administer the program.

(d) SELECTION AND ELIGIBILITY REQUIREMENTS FOR DELTA LOAN GUARANTEES.—

(1) IN GENERAL.—The selection criteria and eligibility requirements set forth in this subsection shall be applied in the selection of small business concerns to receive loan guarantees under the DELTA program.

(2) SELECTION CRITERIA.—The criteria used for the selection of a small business concern to receive a loan guarantee under this section are as follows:

(A) The selection criteria established under the memorandum of understanding referred to in subsection (a)(3).

(B) The extent to which the loans to be guaranteed would support the retention of defense workers whose employment would otherwise be permanently or temporarily terminated as a result of reductions in expenditures by the United States for defense, the termination or cancellation of a defense contract, the failure to proceed with an approved major weapon system, the merger or consolidation of the operations of a defense contractor, or the closure or realignment of a military installation.

(C) The extent to which the loans to be guaranteed would stimulate job creation and new economic activities in communities most adversely affected by reductions in expenditures by the United States for defense, the termination or cancellation of a defense contract, the failure to proceed with an approved major weapon system, the merger or consolidation of the operations of a defense contractor, or the closure or realignment of a military installation.

(D) The extent to which the loans to be guaranteed would be used to acquire (or permit the use of other funds to acquire) capital equipment to modernize or expand the facilities of the borrower to enable the borrower to remain in the national technology and industrial base available to the Department of Defense.

(3) ELIGIBILITY REQUIREMENTS.—To be eligible for a loan guarantee under the DELTA program, a borrower must demonstrate to the satisfaction of the Administrator that, during any 1 of the 5 preceding operating years of the borrower, not less than 25 percent of the value of the borrower's sales were derived from—

(A) contracts with the Department of Defense or the defense-related activities of the Department of Energy; or

(B) subcontracts in support of defense-related prime contracts.

(e) MAXIMUM AMOUNT OF LOAN PRINCIPAL.—With respect to each borrower, the maximum amount of loan principal for which the Administrator may provide a guarantee under this section during a fiscal year may not exceed $1,250,000.

(f) LOAN GUARANTY RATE.—The maximum allowable guarantee percentage for loans guaranteed under this section may not exceed 80 percent.

(g) FUNDING.—

(1) IN GENERAL.—The funds that have been made available for loan guarantees under the DELTA program and have been transferred from the Department of Defense to the Small Business Administration before the date of the enactment of this Act shall be used for carrying out the DELTA program under this section.

(2) CONTINUED AVAILABILITY OF EXISTING FUNDS.—The funds made available under the second proviso under the heading ''RESEARCH, DEVELOPMENT, TEST AND EVALUATION, DEFENSE-WIDE'' in Public Law 103–335 (108 Stat. 2613) shall be available until expended—

(A) to cover the costs (as defined in section 502(5) of the Federal Credit Reform Act of 1990 (2 U.S.C. 661a(5))) of loan guarantees issued under this section; and

(B) to cover the reasonable costs of the administration of the loan guarantees.

SEC. 508. VERY SMALL BUSINESS CONCERNS.

Section 304(i) of the Small Business Administration Reauthorization and Amendments Act of 1994 (15 U.S.C. 644 note) is amended by striking ''September 30, 1998'' and inserting ''September 30, 2000''.

SEC. 509. TRADE ASSISTANCE PROGRAM FOR SMALL BUSINESS CONCERNS ADVERSELY AFFECTED BY NAFTA.

The Administrator shall coordinate Federal assistance in order to provide counseling to small business concerns adversely affected by the North American Free Trade Agreement.

TITLE VI—HUBZONE PROGRAM

SEC. 601. SHORT TITLE.

This title may be cited as the ''HUBZone Act of 1997''.

SEC. 602. HISTORICALLY UNDERUTILIZED BUSINESS ZONES.

(a) DEFINITIONS.—Section 3 of the Small Business Act (15 U.S.C. 632) (as amended by section 412 of this Act) is amended by adding at the end the following:

''(p) DEFINITIONS RELATING TO HUBZONES.—In this Act:

''(1) HISTORICALLY UNDERUTILIZED BUSINESS ZONE.—The term 'historically underutilized business zone' means any area located within 1 or more—

''(A) qualified census tracts;

''(B) qualified nonmetropolitan counties; or

''(C) lands within the external boundaries of an Indian reservation.

''(2) HUBZONE.—The term 'HUBZone' means a historically underutilized business zone.

''(3) HUBZONE SMALL BUSINESS CONCERN.—The term 'HUBZone small business concern' means a small business concern—

''(A) that is owned and controlled by 1 or more persons, each of whom is a United States citizen; and

''(B) the principal office of which is located in a HUBZone; or

''(4) QUALIFIED AREAS.—

''(A) QUALIFIED CENSUS TRACT.—The term 'qualified census tract' has the meaning given that term in section 42(d)(5)(C)(ii)(I) of the Internal Revenue Code of 1986.

''(B) QUALIFIED NONMETROPOLITAN COUNTY.—The term 'qualified nonmetropolitan county' means any county—

''(i) that, based on the most recent data available from the Bureau of the Census of the Department of Commerce—

''(I) is not located in a metropolitan statistical area (as defined in section 143(k)(2)(B) of the Internal Revenue Code of 1986); and

''(II) in which the median household income is less than 80 percent of the nonmetropolitan State median household income; or

''(ii) that, based on the most recent data available from the Secretary of Labor, has an unemployment rate that is not less than 140 percent of the statewide average unemployment rate for the State in which the county is located.

''(5) QUALIFIED HUBZONE SMALL BUSINESS CONCERN.—

''(A) IN GENERAL.—A HUBZone small business concern is 'qualified', if—

''(i) the small business concern has certified in writing to the Administrator (or the Administrator otherwise determines, based on information submitted to the Administrator by the small business concern, or based on certification procedures, which shall be established by the Administration by regulation) that—

''(I) it is a HUBZone small business concern;

''(II) not less than 35 percent of the employees of the small business concern reside in a HUBZone, and the small business concern will attempt to maintain this employment percentage during the performance of any contract awarded to the small business concern on the basis of a preference provided under section 31(b); and

''(III) with respect to any subcontract entered into by the small business concern pursuant to a contract awarded to the small business concern under section 31, the small business concern will ensure that—

''(aa) in the case of a contract for services (except construction), not less than 50 percent of the cost of contract performance incurred for personnel will be expended for its employees or for employees of other HUBZone small business concerns; and

''(bb) in the case of a contract for procurement of supplies (other than procurement from a regular dealer in such supplies), not less than 50 percent of the cost of manufacturing the supplies (not including the cost of materials) will be incurred in connection with the performance of the contract in a HUBZone by 1 or more HUBZone small business concerns; and

''(ii) no certification made or information provided by the small business concern under clause (i) has been, in accordance with the procedures established under section 31(c)(1)—

''(I) successfully challenged by an interested party; or

''(II) otherwise determined by the Administrator to be materially false.

''(B) CHANGE IN PERCENTAGES.—The Administrator may utilize a percentage other than the percentage specified in under item (aa) or (bb) of subparagraph (A)(i)(III), if the Administrator determines that such action is necessary to reflect conventional industry practices among small business concerns that are below the numerical size standard for businesses in that industry category.

''(C) CONSTRUCTION AND OTHER CONTRACTS.—The Administrator shall promulgate final regulations imposing requirements that are similar to those specified in subclauses (IV) and (V) of subparagraph (A)(i) on contracts for general and specialty construction, and on contracts for any other industry category that would not otherwise be subject to those requirements. The percentage applicable to any such requirement shall be determined in accordance with subparagraph (B).

''(D) LIST OF QUALIFIED SMALL BUSINESS CONCERNS.—The Administrator shall establish and maintain a list of qualified HUBZone small business concerns, which list shall, to the extent practicable—

''(i) include the name, address, and type of business with respect to each such small business concern;

''(ii) be updated by the Administrator not less than annually; and

''(iii) be provided upon request to any Federal agency or other entity.''.

(b) FEDERAL CONTRACTING.—

(1) IN GENERAL.—The Small Business Act (15 U.S.C. 631 et seq.) is amended—

(A) by redesignating section 31 as section 32; and

(B) by inserting after section 30 the following:

''SEC. 31. HUBZONE PROGRAM.

''(a) IN GENERAL.—There is established within the Administration a program to be carried out by the Administrator to provide for Federal contracting assistance to qualified HUBZone small business concerns in accordance with this section.

''(b) ELIGIBLE CONTRACTS.—

''(1) DEFINITIONS.—In this subsection—

''(A) the term 'contracting officer' has the meaning given that term in section 27(f)(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 423(f)(5)); and

''(B) the term 'full and open competition' has the meaning given that term in section 4 of the Office of Federal Procurement Policy Act (41 U.S.C. 403).

''(2) AUTHORITY OF CONTRACTING OFFICER.—Notwithstanding any other provision of law—

''(A) a contracting officer may award sole source contracts under this section to any qualified HUBZone small business concern, if—

''(i) the qualified HUBZone small business concern is determined to be a responsible contractor with respect to performance of such contract opportunity, and the contracting officer does not have a reasonable expectation that 2 or more qualified HUBZone small business concerns will submit offers for the contracting opportunity;

''(ii) the anticipated award price of the contract (including options) will not exceed—

''(I) $5,000,000, in the case of a contract opportunity assigned a standard industrial classification code for manufacturing; or

''(II) $3,000,000, in the case of all other contract opportunities; and

''(iii) in the estimation of the contracting officer, the contract award can be made at a fair and reasonable price;

''(B) a contract opportunity shall be awarded pursuant to this section on the basis of competition restricted to qualified HUBZone small business concerns if the contracting officer has a reasonable expectation that not less than 2 qualified HUBZone small business concerns will submit offers and that the award can be made at a fair market price; and

''(C) not later than 5 days from the date the Administration is notified of a procurement officer's decision not to award a contract opportunity under this section to a qualified HUBZone small business concern, the Administrator may notify the contracting officer of the intent to appeal the contracting officer's decision, and within 15 days of such date the Administrator may file a written request for reconsideration of the contracting officer's decision with the Secretary of the department or agency head.

''(3) PRICE EVALUATION PREFERENCE IN FULL AND OPEN COMPETITIONS.—In any case in which a contract is to be awarded on the basis of full and open competition, the price offered by a qualified HUBZone small business concern shall be deemed as being lower than the price offered by another offeror (other than another small business concern), if the price offered by the qualified HUBZone small business concern is not more than 10 percent higher than the price offered by the otherwise lowest, responsive, and responsible offeror.

''(4) RELATIONSHIP TO OTHER CONTRACTING PREFERENCES.—A procurement may not be made from a source on the basis of a preference provided in paragraph (2) or (3), if the procurement would otherwise be made from a different source under section 4124 or 4125 of title 18, United States Code, or the Javits-Wagner-O'Day Act (41 U.S.C. 46 et seq.).

''(c) ENFORCEMENT; PENALTIES.—

''(1) VERIFICATION OF ELIGIBILITY.—In carrying out this section, the Administrator shall establish procedures relating to—

''(A) the filing, investigation, and disposition by the Administration of any challenge to the eligibility of a small business concern to receive assistance under this section (including a challenge, filed by an interested party, relating to the veracity of a certification made or information provided to the Administration by a small business concern under section 3(p)(5)); and

''(B) verification by the Administrator of the accuracy of any certification made or information provided to the Administration by a small business concern under section 3(p)(5).

''(2) EXAMINATIONS.—The procedures established under paragraph (1) may provide for program examinations (including random program examinations) by the Administrator of any small business concern making a certification or providing information to the Administrator under section 3(p)(5).

''(3) PROVISION OF DATA.—Upon the request of the Administrator, the Secretary of Labor, the Secretary of Housing and Urban Development, and the Secretary of the Interior (or the Assistant Secretary for Indian Affairs), shall promptly provide to the Administrator such information as the Administrator determines to be necessary to carry out this subsection.

''(4) PENALTIES.—In addition to the penalties described in section 16(d), any small business concern that is determined by the Administrator to have misrepresented the status of that concern as a 'HUBZone small business concern' for purposes of this section, shall be subject to—

''(A) section 1001 of title 18, United States Code; and

''(B) sections 3729 through 3733 of title 31, United States Code.''.

(2) INITIAL LIMITED APPLICABILITY.—During the period beginning on the date of enactment of this Act and ending on September 30, 2000, section 31 of the Small Business Act (as added by paragraph (1) of this subsection) shall apply only to procurements by—

(A) the Department of Defense;

(B) the Department of Agriculture;

(C) the Department of Health and Human Services;

(D) the Department of Transportation;

(E) the Department of Energy;

(F) the Department of Housing and Urban Development;

(G) the Environmental Protection Agency;

(H) the National Aeronautics and Space Administration;

(I) the General Services Administration; and

(J) the Department of Veterans Affairs.

SEC. 603. TECHNICAL AND CONFORMING AMENDMENTS TO THE SMALL BUSINESS ACT.

(a) PERFORMANCE OF CONTRACTS.—Section 8(d) of the Small Business Act (15 U.S.C. 637(d)) is amended—

(1) in paragraph (1)—

(A) in the first sentence, by striking '',, small business concerns owned and controlled by socially and economically disadvantaged individuals'' and inserting '', qualified HUBZone small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals''; and

(B) in the second sentence, by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,'';

(2) in paragraph (3)—

(A) by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,'' each place that term appears; and

(B) by adding at the end the following:

''(F) In this contract, the term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act.'';

(3) in paragraph (4)(E), by striking ''small business concerns and'' and inserting ''small business concerns, qualified HUBZone small business concerns, and'';

(4) in paragraph (6), by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,'' each place that term appears; and

(5) in paragraph (10), by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,''.

(b) AWARDS OF CONTRACTS.—Section 15 of the Small Business Act (15 U.S.C. 644) is amended—

(1) in subsection (g)(1)—

(A) by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,'' each place that term appears;

(B) in the second sentence, by striking ''20 percent'' and inserting ''23 percent''; and

(C) by inserting after the second sentence the following: ''The Governmentwide goal for participation by qualified HUBZone small business concerns shall be established at not less than 1 percent of the total value of all prime contract awards for fiscal year 1999, not less than 1.5 percent of the total value of all prime contract awards for fiscal year 2000, not less than 2 percent of the total value of all prime contract awards for fiscal year 2001, not less than 2.5 percent of the total value of all prime contract awards for fiscal year 2002, and not less than 3 percent of the total value of all prime contract awards for fiscal year 2003 and each fiscal year thereafter.'';

(2) in subsection (g)(2)—

(A) in the first sentence, by striking '',, by small business concerns owned and controlled by socially and economically disadvantaged individuals'' and inserting '', by qualified HUBZone small business concerns, by small business concerns owned and controlled by socially and economically disadvantaged individuals'';

(B) in the second sentence, by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,''; and

(C) in the fourth sentence, by striking ''by small business concerns owned and controlled by socially and economically disadvantaged individuals and participation by small business concerns owned and controlled by women'' and inserting ''by qualified HUBZone small business concerns, by small business concerns owned and controlled by socially and economically disadvantaged individuals, and by small business concerns owned and controlled by women''; and

(3) in subsection (h), by inserting ''qualified HUBZone small business concerns,'' after ''small business concerns,'' each place that term appears.

(c) OFFENSES AND PENALTIES.—Section 16 of the Small Business Act (15 U.S.C. 645) is amended—

(1) in subsection (d)(1)—

(A) by inserting '', a 'qualified HUBZone small business concern','' after '''small business concern',''; and

(B) in subparagraph (A), by striking ''section 9 or 15'' and inserting ''section 9, 15, or 31''; and

(2) in subsection (e), by inserting '', a 'HUBZone small business concern','' after '''small business concern',''.

SEC. 604. OTHER TECHNICAL AND CONFORMING AMENDMENTS.

(a) TITLE 10, UNITED STATES CODE.—Section 2323 of title 10, United States Code, is amended—

(1) in subsection (a)(1)(A), by inserting before the semicolon the following: '', and qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act)''; and

(2) in subsection (f)(1), by inserting ''or as a qualified HUBZone small business concern (as defined in section 3(p) of the Small Business Act)'' after ''(as described in subsection (a))''.

(b) FEDERAL HOME LOAN BANK ACT.—Section 21A(b)(13) of the Federal Home Loan Bank Act (12 U.S.C. 1441a(b)(13)) is amended—

(1) by striking ''concerns and small'' and inserting ''concerns, small''; and

(2) by inserting '', and qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act)'' after ''disadvantaged individuals''.

(c) SMALL BUSINESS ECONOMIC POLICY ACT OF 1980.—Section 303(e) of the Small Business Economic Policy Act of 1980 (15 U.S.C. 631b(e)) is amended—

(1) in paragraph (1), by striking ''and'' at the end;

(2) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(3) by adding at the end the following:

''(3) qualified HUBZone small business concern (as defined in section 3(p) of the Small Business Act).''.

(d) SMALL BUSINESS INVESTMENT ACT OF 1958.—Section 411(c)(3)(B) of the Small Business Investment Act of 1958 (15 U.S.C. 694b(c)(3)(B)) is amended by inserting before the semicolon the following: '', or to a qualified HUBZone small business concern (as defined in section 3(p) of the Small Business Act)''.

(e) TITLE 31, UNITED STATES CODE.—

(1) CONTRACTS FOR COLLECTION SERVICES.—Section 3718(b) of title 31, United States Code, is amended—

(A) in paragraph (1)(B), by inserting ''and law firms that are qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act)'' after ''disadvantaged individuals''; and

(B) in paragraph (3)—

(i) in the first sentence, by inserting before the period ''and law firms that are qualified HUBZone small business concerns'';

(ii) in subparagraph (A), by striking ''and'' at the end;

(iii) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(iv) by adding at the end the following:

''(C) the term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act.''.

(2) PAYMENTS TO LOCAL GOVERNMENTS.—Section 6701(f) of title 31, United States Code, is amended—

(A) in paragraph (1)—

(i) in subparagraph (A), by striking ''and'' at the end;

(ii) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(C) qualified HUBZone small business concerns.''; and

(B) in paragraph (3)—

(i) in subparagraph (A), by striking ''and'' at the end;

(ii) in subparagraph (B), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(C) the term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act (15 U.S.C. 632(o)).''.

(3) REGULATIONS.—Section 7505(c) of title 31, United States Code, is amended by striking ''small business concerns and'' and inserting ''small business concerns, qualified HUBZone small business concerns, and''.

(f) OFFICE OF FEDERAL PROCUREMENT POLICY ACT.—

(1) ENUMERATION OF INCLUDED FUNCTIONS.—Section 6(d) of the Office of Federal Procurement Policy Act (41 U.S.C. 405(d)) is amended—

(A) in paragraph (11), by inserting ''qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act),'' after ''small businesses,''; and

(B) in paragraph (12), by inserting ''qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act (15 U.S.C. 632(o)),'' after ''small businesses,''.

(2) PROCUREMENT DATA.—Section 502 of the Women's Business Ownership Act of 1988 (41 U.S.C. 417a) is amended—

(A) in subsection (a)—

(i) in the first sentence, by inserting ''the number of qualified HUBZone small business concerns,'' after ''Procurement Policy''; and

(ii) by inserting a comma after ''women''; and

(B) in subsection (b), by inserting after ''section 204 of this Act'' the following: '', and the term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act (15 U.S.C. 632(o)).''.

(g) ENERGY POLICY ACT OF 1992.—Section 3021 of the Energy Policy Act of 1992 (42 U.S.C. 13556) is amended—

(1) in subsection (a)—

(A) in paragraph (2), by striking ''or'';

(B) in paragraph (3), by striking the period and inserting ''; or''; and

(C) by adding at the end the following:

''(4) qualified HUBZone small business concerns.''; and

(2) in subsection (b), by adding at the end the following:

''(3) The term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act (15 U.S.C. 632(o)).''.

(h) TITLE 49, UNITED STATES CODE.—

(1) PROJECT GRANT APPLICATION APPROVAL CONDITIONED ON ASSURANCES ABOUT AIRPORT OPERATION.—Section 47107(e) of title 49, United States Code, is amended—

(A) in paragraph (1), by inserting before the period ''or qualified HUBZone small business concerns (as defined in section 3(p) of the Small Business Act)'';

(B) in paragraph (4)(B), by inserting before the period ''or as a qualified HUBZone small business concern (as defined in section 3(p) of the Small Business Act)''; and

(C) in paragraph (6), by inserting ''or a qualified HUBZone small business concern (as defined in section 3(p) of the Small Business Act)'' after ''disadvantaged individual''.

(2) MINORITY AND DISADVANTAGED BUSINESS PARTICIPATION.—Section 47113 of title 49, United States Code, is amended—

(A) in subsection (a)—

(i) in paragraph (1), by striking the period at the end and inserting a semicolon;

(ii) in paragraph (2), by striking the period at the end and inserting ''; and''; and

(iii) by adding at the end the following:

''(3) the term 'qualified HUBZone small business concern' has the meaning given that term in section 3(p) of the Small Business Act (15 U.S.C. 632(o)).''; and

(B) in subsection (b), by inserting before the period ''or qualified HUBZone small business concerns''.

SEC. 605. REGULATIONS.

(a) IN GENERAL.—Not later than 180 days after the date of enactment of this Act, the Administrator shall publish in the Federal Register such final regulations as may be necessary to carry out this title and the amendments made by this title.

(b) FEDERAL ACQUISITION REGULATION.—Not later than 180 days after the date on which final regulations are published under subsection (a), the Federal Acquisition Regulatory Council shall amend the Federal Acquisition Regulation in order to ensure consistency between the Federal Acquisition Regulation, this title and the amendments made by this title, and the final regulations published under subsection (a).

SEC. 606. REPORT.

Not later than March 1, 2002, the Administrator shall submit to the Committees a report on the implementation of the HUBZone program established under section 31 of the Small Business Act (as added by section 602(b) of this title) and the degree to which the HUBZone program has resulted in increased employment opportunities and an increased level of investment in HUBZones (as defined in section 3(p) of the Small Business Act (15 U.S.C. 632(p)), as added by section 602(a) of this title).

SEC. 607. AUTHORIZATION OF APPROPRIATIONS.

Section 20 of the Small Business Act (15 U.S.C. 631 note) (as amended by section 101 of this Act) is amended—

(1) in subsection (c), by adding at the end the following:

''(3) HUBZONE PROGRAM.—There are authorized to be appropriated to the Administration to carry out the program under section 31, $5,000,000 for fiscal year 1998.'';

(2) in subsection (d), by adding at the end the following:

''(3) HUBZONE PROGRAM.—There are authorized to be appropriated to the Administration to carry out the program under section 31, $5,000,000 for fiscal year 1999.''; and

(3) in subsection (e), by adding at the end the following:

''(3) HUBZONE PROGRAM.—There are authorized to be appropriated to the Administration to carry out the program under section 31, $5,000,000 for fiscal year 2000.''.

TITLE VII—SERVICE DISABLED VETERANS

SEC. 701. PURPOSES.

The purposes of this title are—

(1) to foster enhanced entrepreneurship among eligible veterans by providing increased opportunities;

(2) to vigorously promote the legitimate interests of small business concerns owned and controlled by eligible veterans; and

(3) to ensure that those concerns receive fair consideration in purchases made by the Federal Government.

SEC. 702. DEFINITIONS.

In this title:

(1) ELIGIBLE VETERAN.—The term ''eligible veteran'' means a disabled veteran (as defined in section 4211(3) of title 38, United States Code).

(2) SMALL BUSINESS CONCERN OWNED AND CONTROLLED BY ELIGIBLE VETERANS.—The term ''small business concern owned and controlled by eligible veterans'' means a small business concern (as defined in section 3 of the Small Business Act)—

(A) that is at least 51 percent owned by 1 or more eligible veterans, or in the case of a publicly owned business, at least 51 percent of the stock of which is owned by 1 or more eligible veterans; and

(B) whose management and daily business operations are controlled by eligible veterans.

SEC. 703. REPORT BY SMALL BUSINESS ADMINISTRATION.

(a) STUDY AND REPORT.—

(1) IN GENERAL.—Not later than 9 months after the date of enactment of this Act, the Administrator shall conduct a comprehensive study and submit to the Committees a final report containing findings and recommendations of the Administrator on—

(A) the needs of small business concerns owned and controlled by eligible veterans;

(B) the availability and utilization of Administration programs by small business concerns owned and controlled by eligible veterans;

(C) the percentage, and dollar value, of Federal contracts awarded to small business concerns owned and controlled by eligible veterans in the preceding 5 fiscal years; and

(D) methods to improve Administration and other agency programs to serve the needs of small business concerns owned and controlled by eligible veterans.

(2) CONTENTS.—The report under paragraph (1) shall include recommendations to Congress concerning the need for legislation and recommendations to the Office of Management and Budget, relevant offices within the Administration, and the Department of Veterans Affairs.

(b) CONDUCT OF STUDY.—In carrying out subsection (a), the Administrator—

(1) may conduct surveys of small business concerns owned and controlled by eligible veterans and service disabled veterans, including those who have sought financial assistance or other services from the Administration;

(2) shall consult with the appropriate committees of Congress, relevant groups and organizations in the nonprofit sector, and Federal or State government agencies; and

(3) shall have access to any information within other Federal agencies that pertains to such veterans and their small businesses, unless such access is specifically prohibited by law.

SEC. 704. INFORMATION COLLECTION.

After the date of issuance of the report required by section 703(a), the Secretary of Veterans Affairs shall, in consultation with the Assistant Secretary for Veterans' Employment and Training and the Administrator, engage in efforts each fiscal year to identify small business concerns owned and controlled by eligible veterans in the United States. The Secretary shall inform each small business concern identified under this section that information on Federal procurement is available from the Administrator.

SEC. 705. STATE OF SMALL BUSINESS REPORT.

Section 303(b) of the Small Business Economic Policy Act of 1980 (15 U.S.C. 631b(b)) is amended by striking ''and female-owned businesses'' and inserting '', female-owned, and veteran-owned businesses''.

SEC. 706. LOANS TO VETERANS.

Section 7(a) of the Small Business Act (15 U.S.C. 636(a)) is amended by inserting after paragraph (7) the following:

''(8) The Administration may make loans under this subsection to small business concerns owned and controlled by disabled veterans (as defined in section 4211(3) of title 38, United States Code).''.

SEC. 707. ENTREPRENEURIAL TRAINING, COUNSELING, AND MANAGEMENT ASSISTANCE.

The Administrator shall take such actions as may be necessary to ensure that small business concerns owned and controlled by eligible veterans have access to programs established under the Small Business Act that provide entrepreneurial training, business development assistance, counseling, and management assistance to small business concerns, including, among others, the Small Business Development Center program and the Service Corps of Retired Executives (SCORE) program.

SEC. 708. GRANTS FOR ELIGIBLE VETERANS' OUTREACH PROGRAMS.

Section 8(b) of the Small Business Act (15 U.S.C. 637(b)) is amended—

(1) in paragraph (15), by striking ''and'' at the end;

(2) in the first paragraph designated as paragraph (16), by striking the period at the end and inserting ''; and''; and

(3) by striking the second paragraph designated as paragraph (16) and inserting the following:

''(17) to make grants to, and enter into contracts and cooperative agreements with, educational institutions, private businesses, veterans' nonprofit community-based organizations, and Federal, State, and local departments and agencies for the establishment and implementation of outreach programs for disabled veterans (as defined in section 4211(3) of title 38, United States Code).''.

SEC. 709. OUTREACH FOR ELIGIBLE VETERANS.

The Administrator, the Secretary of Veterans Affairs, and the Assistant Secretary of Labor for Veterans' Employment and Training, shall develop and implement a program of comprehensive outreach to assist eligible veterans, which program shall include business training and management assistance, employment and relocation counseling, and dissemination of information on veterans' benefits and veterans' entitlements.

The SPEAKER pro tempore, Mr. LATHAM, recognized Mr. TALENT and Mr. LAFALCE, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said amendment?

The SPEAKER pro tempore, Mr. LATHAM, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said amendment of the Senate to the amendment of the House was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said amendment to the amendment the house was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.15 MICROCREDIT FOR SELF-RELIANCE

Mr. GILMAN moved to suspend the rules and pass the bill (H.R. 1129) to establish a program to provide assistance for programs of credit and other assistance for microenterprises in developing countries, and for other purposes; as amended.

The SPEAKER pro tempore, Mr. LATHAM, recognized Mr. GILMAN and Mr. GEJDENSON, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. LATHAM, announced that two-thirds of the Members present had voted in the affirmative.

Mr. GILMAN demanded that the vote be taken by the yeas and nays, which demand was supported by one-fifth of the Members present, so the yeas and nays were ordered.

The SPEAKER pro tempore, Mr. LATHAM, pursuant to clause 5, rule I, announced that further proceedings on the motion were postponed.

¶130.16 RELIGIOUS PERSECUTION IN GERMANY

Mr. GILMAN moved to suspend the rules and agree to the following concurrent resolution (H. Con. Res. 22); as amended:

Whereas since World War II, Germany has been a friend and ally of the United States;

Whereas German government discrimination against members of minority religious groups, particularly against United States citizens, has the potential to harm the relationship between Germany and the United States;

Whereas artists from the United States associated with certain religious minorities have been denied the opportunity to perform, have been the subjects of boycotts, and have been the victims of a widespread and well-documented pattern and practice of discrimination by German Federal, State, local, and party officials;

Whereas the 1993, 1994, 1995, and 1996 United States Department of State Country Reports on Human Rights in Germany all noted government discrimination against members of the Church of Scientology in Germany;

Whereas the German State of Baden-Wuerttemberg barred Chic Corea, the Grammy Award-winning American jazz pianist, from performing his music during the

World Athletics Championship in 1993, and in 1996 the State of Bavaria declared its intention to bar Mr. Corea from all future performances at State sponsored events solely because he is a member of the Church of Scientology;

Whereas the Young Union of the Christian Democratic Union and the Social Democratic Party orchestrated boycotts of the movies ''Phenomenon'' and ''Mission Impossible'' solely because the lead actors, Americans John Travolta and Tom Cruise, are members of the Church of Scientology;

Whereas members of the Young Union of the Christian Democratic Union disrupted a 1993 performance by the American folk music group Golden Bough by storming the stage solely because the musicians are members of the Church of Scientology;

Whereas the Evangelical Christian Church of Cologne, led by an American clergyman, Dr. Terry Jones, had its tax-exempt status revoked by the German government with the reason being that the church benefits to society were of ''no spiritual, cultural, or material value'';

Whereas the German government is constitutionally obligated to remain neutral on religious matters, yet has violated this neutrality by supporting and distributing information to the general public that gives the impression that ''sect-experts'', who are only critical of all but the major churches, are in a position to provide the public with fair, objective, and politically neutral information about minority religions;

Whereas the Jehovah's Witnesses' application for recognition as a corporation under public law, which would have put them on equal legal status with the Catholic and Protestant churches, was denied by the Federal Administrative Court because the church's doctrine of political neutrality was considered to be antidemocratic;

Whereas government officials and ''sect-experts'' are using the decision denying the Jehovah's Witnesses recognition as a corporation under public law as a justification for discriminatory acts against the Jehovah's Witnesses, despite the fact that a constitutional complaint is still pending before the German Constitutional Court;

Whereas adherents of the Muslim faith have reported that they are routinely subject to police violence and intimidation because of their ethnic and religious affiliation;

Whereas the 1994 and 1995 Reports to the Human Rights Commission of the United Nations on the application of the Declaration on the Elimination of All Forms of Intolerance and of Discrimination Based on Religion and Belief by the Special Rapporteur for Religious Intolerance criticized Germany for restricting the religious liberty of certain minority religious groups;

Whereas Germany, as a signatory to the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the Helsinki Accords, is obliged to refrain from religious discrimination and to foster a climate of tolerance; and

Whereas Germany's policy of discrimination against minority religions violates German obligations under the Universal Declaration of Human Rights, the International Covenant on Civil and Political Rights, and the Helsinki Accords: Now, therefore, be it

Resolved by the House of Representatives (the Senate concurring), That the Congress—

(1) continues to hold Germany responsible for protecting the rights of United States citizens who are living, performing, doing business, or traveling in Germany, in a manner consistent with Germany's obligations under international agreements to which Germany is a signatory;

(2) deplores the actions and statements of Federal, State, local, and party officials in Germany which have fostered an atmosphere of intolerance toward certain minority religious groups;

(3) expresses concern that artists from the United States who are members of minority religious groups continue to experience German government discrimination;

(4) urges the German government to take the action necessary to protect the rights guaranteed to members of minority religious groups by international covenants to which Germany is a signatory; and

(5) calls upon the President of the United States—

(A) to assert the concern of the United States Government regarding German government discrimination against members of minority religious groups;

(B) to emphasize that the United States regards the human rights practices of the Government of Germany, particularly its treatment of American citizens who are living, performing, doing business, or traveling in Germany, as a significant factor in the United States Government's relations with the Government of Germany; and

(C) to encourage other governments to appeal to the Government of Germany, and to cooperate with other governments and international organizations, including the United Nations and its agencies, in efforts to protect the rights of foreign citizens and members of minority religious groups in Germany.

The SPEAKER pro tempore, Mr. LATHAM, recognized Mr. GILMAN and Mr. BEREUTER, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said concurrent resolution, as amended?

The SPEAKER pro tempore, Mr. PETRI, announced that two-thirds of the Members present had voted in the affirmative.

On a division demanded by Mr. BEREUTER, there appeared, yeas—3, nays—12.

Mr. SALMON demanded that the vote be taken by the yeas and nays, which demand was supported by one-fifth of the Members present, so the yeas and nays were ordered.

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5, rule I, announced that further proceedings on the motion were postponed.

¶130.17 EXPO 2000

Mr. BEREUTER moved to suspend the rules and agree to the following concurrent resolution (H. Con. Res. 139); as amended:

Whereas Germany has invited nations, international and non-governmental organizations, and individuals from around the world to participate in EXPO 2000, a global town hall meeting to be hosted in the year 2000, in Hanover, Germany, for the purpose providing a forum for worldwide dialogue on the challenges, goals, and solutions for the sustainable development of mankind in the 21st century;

Whereas the theme of EXPO 2000 is ''Humankind-Nature-Technology'';

Whereas EXPO 2000 will take place in the heart of the newly unified, free, and democratic Europe;

Whereas Germany has established a stable democracy and a pluralistic society in the heart of Europe;

Whereas more than 40,000,000 people in the United States can trace their ancestry to Germany, and in 1983 the United States and Germany celebrated the Tri-Centennial of immigration of Germans into the United States;

Whereas Germany has been a close political and military ally of the United States for nearly five decades and has been a driving force with respect to the political, monetary, and economic integration of Europe;

Whereas the United States, as a leading political, intellectual, and economic power, maintains a strong interest in the worldwide strengthening of political freedom and human rights, open market economies, and technological advancement throughout the world; and

Whereas the United States is eager to share with the global community the vast and promising public and private efforts being made to prepare for the next century; Now, therefore, be it

Resolved by the House of Representatives (the Senate concurring), That it is the sense of Congress that the United States—

(1) should fully participate in EXPO 2000, a global town hall meeting to be hosted in the year 2000, in Hanover, Germany, for the purpose of providing a forum for worldwide dialogue on the challenges, goals, and solutions for the sustainable development of mankind in the 21st century; and

(2) should encourage the academic community and the private sector in the United States to support this worthwhile undertaking.

The SPEAKER pro tempore, Mr. PETRI, recognized Mr. BEREUTER and Mr. PAYNE, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said concurrent resolution, as amended?

The SPEAKER pro tempore, Mr. PETRI, announced that two-thirds of the Members present had voted in the affirmative.

Mr. BEREUTER demanded that the vote be taken by the yeas and nays, which demand was supported by one-fifth of the Members present, so the yeas and nays were ordered.

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5, rule I, announced that further proceedings on the motion were postponed.

¶130.18 FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate agrees to the report of the committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 830) ''An Act to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes.''.

¶130.19 H.R. 2232—UNFINISHED BUSINESS

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5 of rule I, announced the unfinished business to be the question on the passage of the bill (H.R. 2232) to provide for increased international broadcasting activities to China.

The question being put,

Will the House pass said bill?

The vote was taken by electronic device.

It was decided in the affirmative ..... { Yeas ..... 401 / Nays 21

¶130.20 [Roll No. 623]

YEAS—401

Abercrombie
Ackerman
Aderholt
Allen
Andrews
Archer
Armey
Bachus
Baesler
Baker
Baldacci
Ballenger
Barcia
Barrett (NE)
Barrett (WI)
Bartlett
Barton
Bass
Bateman
Becerra
Bentsen
Bereuter
Berman
Berry
Bilbray
Bilirakis
Bishop
Blagojevich
Bliley
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonior
Bono
Borski
Boswell
Boucher
Boyd
Brady
Brown (CA)
Brown (FL)
Brown (OH)
Bryant
Bunning
Burr
Burton
Buyer
Callahan
Calvert
Camp
Campbell
Canady
Cannon
Cardin
Carson
Castle
Chabot
Chambliss
Chenoweth
Christensen
Clayton
Clement
Clyburn
Coble
Coburn
Collins
Combest
Condit
Conyers
Cook
Cooksey
Costello
Cox
Coyne
Cramer
Crane
Crapo
Cummings
Cunningham
Danner
Davis (FL)
Davis (IL)
Davis (VA)
Deal
DeGette
Delahunt
DeLauro
DeLay
Dellums
Deutsch
Diaz-Balart
Dickey
Dicks
Dingell
Dixon
Doggett
Dooley
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Emerson
Engel
English
Ensign
Eshoo
Etheridge
Evans
Everett
Ewing
Farr
Fawell
Fazio
Filner
Flake
Foglietta
Foley
Forbes
Ford
Fossella
Fowler
Fox
Frank (MA)
Franks (NJ)
Frelinghuysen
Frost
Furse
Gallegly
Ganske
Gejdenson
Gekas
Gephardt
Gibbons
Gilchrest
Gilman
Goode
Goodlatte
Goodling
Gordon
Goss
Graham
Granger
Green
Greenwood
Gutierrez
Gutknecht
Hall (OH)
Hall (TX)
Hamilton
Hansen
Harman
Hastert
Hastings (FL)
Hastings (WA)
Hayworth
Hefley
Hefner
Herger
Hill
Hilleary
Hilliard
Hinchey
Hinojosa
Hobson
Hoekstra
Holden
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hutchinson
Hyde
Inglis
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Jenkins
John
Johnson (CT)
Johnson (WI)
Johnson, E. B.
Jones
Kanjorski
Kaptur
Kasich
Kelly
Kennedy (MA)
Kennedy (RI)
Kennelly
Kildee
Kilpatrick
Kim
Kind (WI)
King (NY)
Kingston
Kleczka
Klink
Knollenberg
Kolbe
Kucinich
LaFalce
LaHood
Lampson
Lantos
Largent
Latham
LaTourette
Lazio
Leach
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
Livingston
LoBiondo
Lofgren
Lowey
Lucas
Luther
Maloney (CT)
Maloney (NY)
Manton
Manzullo
Markey
Martinez
Mascara
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McDade
McGovern
McHale
McHugh
McInnis
McIntosh
McIntyre
McKeon
McKinney
McNulty
Meehan
Meek
Menendez
Metcalf
Mica
Millender-McDonald
Miller (CA)
Miller (FL)
Minge
Mink
Moakley
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Neal
Nethercutt
Ney
Northup
Norwood
Nussle
Oberstar
Obey
Olver
Ortiz
Owens
Oxley
Packard
Pallone
Pappas
Parker
Pascrell
Pastor
Paxon
Payne
Pease
Pelosi
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pitts
Pombo
Pomeroy
Porter
Portman
Poshard
Price (NC)
Pryce (OH)
Quinn
Radanovich
Rahall
Ramstad
Redmond
Regula
Reyes
Riggs
Rivers
Rodriguez
Roemer
Rogan
Rogers
Rohrabacher
Ros-Lehtinen
Rothman
Roybal-Allard
Royce
Rush
Ryun
Sabo
Salmon
Sanchez
Sandlin
Sawyer
Saxton
Scarborough
Schaefer, Dan
Schaffer, Bob
Schumer
Scott
Sessions
Shadegg
Shaw
Shays
Sherman
Shimkus
Sisisky
Skaggs
Skeen
Skelton
Smith (MI)
Smith (NJ)
Smith (OR)
Smith (TX)
Smith, Adam
Smith, Linda
Snowbarger
Snyder
Solomon
Souder
Spence
Spratt
Stabenow
Stark
Stearns
Stenholm
Strickland
Stump
Stupak
Sununu
Talent
Tanner
Tauscher
Tauzin
Taylor (MS)
Thomas
Thompson
Thornberry
Thune
Thurman
Tiahrt
Tierney
Torres
Towns
Traficant
Turner
Upton
Vento
Visclosky
Walsh
Wamp
Waters
Watkins
Watts (OK)
Waxman
Weldon (FL)
Weldon (PA)
Weller
Wexler
Weygand
White
Whitfield
Wicker
Wise
Wolf
Woolsey
Wynn
Young (AK)
Young (FL)

NAYS—21

Bonilla
Chabot
Clay
DeFazio
Duncan
Fattah
Mollohan
Neumann
Obey
Paul
Pickett
Rangel
Sanders
Sanford
Sensenbrenner
Serrano
Shuster
Slaughter
Stokes
Velazquez
Watt (NC)

NOT VOTING—11

Cubin
Gillmor
Gonzalez
Johnson, Sam
Klug
McDermott
Riley
Roukema
Schiff
Taylor (NC)
Yates

So the bill was passed.

A motion to reconsider the vote whereby said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.21 H.R. 1129—UNFINISHED BUSINESS

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5, rule I, announced the further unfinished business to be the motion to suspend the rules and pass the bill (H.R. 1129) to establish a program to provide assistance for programs of credit and other assistance for microenterprises in developing countries, and for other purposes; as amended.

The question being put,

Will the House suspend the rules and pass said bill, as amended?

The vote was taken by electronic device.

It was decided in the affirmative ..... { Yeas ..... 393 / Nays 21

¶130.22 [Roll No. 624]

YEAS—393

Abercrombie
Ackerman
Aderholt
Allen
Andrews
Archer
Armey
Bachus
Baesler
Baker
Baldacci
Ballenger
Barcia
Barrett (NE)
Barrett (WI)
Bartlett
Bass
Bateman
Becerra
Bentsen
Bereuter
Berman
Berry
Bilbray
Bilirakis
Bishop
Blagojevich
Bliley
Blumenauer
Blunt
Boehlert
Boehner
Bonior
Borski
Boswell
Boucher
Brady
Brown (CA)
Brown (FL)
Bryant
Bunning
Burr
Burton
Buyer
Callahan
Calvert
Camp
Campbell
Canady
Cannon
Cardin
Carson
Castle
Chabot
Chambliss
Christensen
Clay
Clayton
Clement
Clyburn
Coburn
Combest
Condit
Conyers
Cook
Cooksey
Costello
Cox
Coyne
Cramer
Crane
Crapo
Cummings
Cunningham
Danner
Davis (FL)
Davis (IL)
Davis (VA)
DeFazio
DeGette
Delahunt
DeLauro
DeLay
Dellums
Deutsch
Diaz-Balart
Dickey
Dicks
Dingell
Dixon
Doggett
Dooley
Doolittle
Doyle
Dreier
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Emerson
Engel
English
Ensign
Eshoo
Etheridge
Evans
Everett
Ewing
Farr
Fattah
Fawell
Fazio
Filner
Flake
Foglietta
Foley
Forbes
Ford
Fossella
Fowler
Fox
Frank (MA)
Franks (NJ)
Frelinghuysen
Frost
Furse
Gallegly
Ganske
Gejdenson
Gekas
Gephardt
Gibbons
Gilchrest
Gilman
Goodlatte
Goodling
Gordon
Goss
Graham
Granger
Green
Greenwood
Gutierrez
Gutknecht
Hall (OH)
Hall (TX)
Hamilton
Hansen
Harman
Hastert
Hastings (FL)
Hastings (WA)
Hayworth
Hefner
Herger
Hilleary
Hilliard
Hinchey
Hinojosa
Hobson
Hoekstra
Holden
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hunter
Hutchinson
Hyde
Inglis
Istook
Jackson (IL)
Jackson-Lee (TX)
Jefferson
John
Johnson (CT)
Johnson (WI)
Johnson, E. B.
Johnson, Sam
Jones
Kanjorski
Kaptur
Kasich
Kelly
Kennedy (MA)
Kennelly
Kildee
Kilpatrick
Kim
Kind (WI)
King (NY)
Kingston
Kleczka
Klink
Knollenberg
Kolbe
Kucinich
LaFalce
LaHood
Lampson
Lantos
Largent
Latham
LaTourette
Lazio
Leach
Levin
Lewis (CA)
Lewis (GA)
Lewis (KY)
Linder
Lipinski
Livingston
LoBiondo
Lofgren
Lowey
Lucas
Luther
Maloney (CT)
Maloney (NY)
Manton
Manzullo
Markey
Martinez
Mascara
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McDade
McGovern
McHale
McHugh
McInnis
McIntosh
McIntyre
McKeon
McKinney
McNulty
Meehan
Meek
Menendez
Mica
Millender-McDonald
Miller (CA)
Miller (FL)
Minge
Mink
Moakley
Mollohan
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Neal
Nethercutt
Neumann
Ney
Northup
Norwood
Nussle
Oberstar
Obey
Olver
Ortiz
Owens
Packard
Pallone
Pappas
Parker
Pascrell
Pastor
Paxon
Payne
Pease
Pelosi
Peterson (MN)
Peterson (PA)
Petri
Pickett
Pitts
Pomeroy
Porter
Portman
Poshard
Price (NC)
Pryce (OH)
Quinn
Radanovich
Rahall
Ramstad
Rangel
Redmond
Regula
Reyes
Riggs
Rivers
Rodriguez
Roemer
Rogan
Rogers
Rohrabacher
Ros-Lehtinen
Rothman

Roybal-Allard
Royce
Rush
Ryun
Sabo
Sanchez
Sanders
Sandlin
Sanford
Sawyer
Saxton
Schaefer, Dan
Schaffer, Bob
Schumer
Scott
Sensenbrenner
Serrano
Shaw
Shays
Sherman
Shimkus
Shuster
Sisisky
Skaggs
Skeen
Skelton
Slaughter
Smith (MI)
Smith (NJ)
Smith (OR)
Smith (TX)
Smith, Adam
Smith, Linda
Snowbarger
Snyder
Solomon
Souder
Spratt
Stabenow
Stark
Stenholm
Stokes
Strickland
Stupak
Sununu
Talent
Tanner
Tauscher
Tauzin
Thomas
Thompson
Thornberry
Thune
Thurman
Tiahrt
Tierney
Torres
Towns
Turner
Upton
Velazquez
Vento
Visclosky
Walsh
Wamp
Waters
Watkins
Watt (NC)
Watts (OK)
Waxman
Weldon (FL)
Weldon (PA)
Weller
Wexler
Weygand
White
Whitfield
Wicker
Wise
Wolf
Woolsey
Wynn
Young (AK)

NAYS—21

Barr
Barton
Bonilla
Chenoweth
Coble
Collins
Deal
Goode
Hefley
Hill
Paul
Pombo
Scarborough
Sessions
Shadegg
Spence
Stearns
Stump
Taylor (MS)
Traficant
Young (FL)

NOT VOTING—19

Bono
Boyd
Brown (OH)
Cubin
Gillmor
Gonzalez
Jenkins
Kennedy (RI)
Klug
McDermott
Metcalf
Oxley
Pickering
Riley
Roukema
Salmon
Schiff
Taylor (NC)
Yates

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill, as amended, was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.23 H. CON. RES. 22—UNFINISHED BUSINESS

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5, rule I, announced the further unfinished business to be the motion to suspend the rules and agree to concurrent resolution (H. Con. Res. 22) expressing the sense of the Congress with respect to the discrimination by the German Government against members of minority religious groups, particularly the continued and increasing discrimination by the German Government against performers, entertainers, and other artists from the United States associated with Scientology; as amended.

The question being put,

Will the House suspend the rules and agree said concurrent resolution, as amended?

The vote was taken by electronic device.

It was decided in the negative ..... { Yeas ..... 101 Nays ..... 318 Answered present 4

¶130.24 [Roll No. 625]

YEAS—101

Abercrombie
Andrews
Becerra
Bilbray
Bilirakis
Bishop
Bonior
Bono
Brown (FL)
Calvert
Carson
Chabot
Christensen
Clay
Clayton
Clyburn
Conyers
Cox
Cummings
Cunningham
Davis (IL)
Davis (VA)
DeGette
Delahunt
DeLauro
Dellums
Deutsch
Diaz-Balart
Doolittle
Dreier
Engel
Ensign
Fattah
Flake
Foley
Ford
Fox
Frost
Gejdenson
Gephardt
Gilman
Gutierrez
Gutknecht
Hall (OH)
Hastings (FL)
Hilliard
Horn
Hulshof
Hutchinson
Jackson (IL)
Jackson-Lee (TX)
Johnson (CT)
Johnson, E. B.
Kelly
Kennelly
Kildee
Kilpatrick
Kim
LaTourette
Lewis (CA)
Maloney (CT)
Maloney (NY)
Martinez
McIntosh
McKinney
Meek
Menendez
Metcalf
Millender-McDonald
Ney
Owens
Pallone
Pappas
Pastor
Payne
Portman
Pryce (OH)
Roemer
Rogan
Rohrabacher
Ros-Lehtinen
Rothman
Royce
Rush
Salmon
Sanford
Scarborough
Schaffer, Bob
Sherman
Slaughter
Stokes
Thompson
Tiahrt
Torres
Towns
Waters
Watt (NC)
Weller
Wexler
Wicker
Wynn

NAYS—318

Ackerman
Aderholt
Allen
Archer
Armey
Bachus
Baesler
Baker
Baldacci
Ballenger
Barcia
Barr
Barrett (NE)
Barrett (WI)
Bartlett
Barton
Bass
Bateman
Bentsen
Bereuter
Berman
Berry
Blagojevich
Bliley
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Borski
Boswell
Boucher
Boyd
Brady
Brown (CA)
Brown (OH)
Bryant
Bunning
Burr
Burton
Buyer
Callahan
Camp
Campbell
Canady
Cannon
Castle
Chambliss
Chenoweth
Clement
Coble
Coburn
Collins
Combest
Condit
Cook
Cooksey
Costello
Coyne
Cramer
Crane
Crapo
Danner
Davis (FL)
Deal
DeFazio
DeLay
Dickey
Dicks
Dingell
Dixon
Doggett
Dooley
Doyle
Duncan
Dunn
Edwards
Ehlers
Ehrlich
Emerson
Eshoo
Etheridge
Evans
Everett
Ewing
Farr
Fawell
Fazio
Filner
Foglietta
Forbes
Fossella
Fowler
Frank (MA)
Franks (NJ)
Frelinghuysen
Furse
Gallegly
Ganske
Gekas
Gibbons
Gilchrest
Goode
Goodlatte
Goodling
Gordon
Goss
Graham
Granger
Green
Greenwood
Hall (TX)
Hamilton
Hansen
Harman
Hastert
Hastings (WA)
Hayworth
Hefley
Hefner
Herger
Hill
Hilleary
Hinchey
Hinojosa
Hobson
Hoekstra
Holden
Hooley
Hostettler
Houghton
Hunter
Hyde
Inglis
Istook
Jefferson
Jenkins
John
Johnson (WI)
Johnson, Sam
Jones
Kanjorski
Kaptur
Kasich
Kennedy (MA)
Kennedy (RI)
Kind (WI)
King (NY)
Kingston
Kleczka
Klink
Knollenberg
Kolbe
LaFalce
LaHood
Lampson
Lantos
Largent
Latham
Lazio
Leach
Levin
Lewis (GA)
Lewis (KY)
Linder
Lipinski
Livingston
LoBiondo
Lofgren
Lowey
Lucas
Luther
Manton
Manzullo
Markey
Mascara
Matsui
McCarthy (MO)
McCarthy (NY)
McCollum
McCrery
McDade
McGovern
McHale
McHugh
McInnis
McIntyre
McKeon
McNulty
Meehan
Mica
Miller (CA)
Miller (FL)
Minge
Mink
Moakley
Mollohan
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Neal
Nethercutt
Neumann
Northup
Norwood
Nussle
Oberstar
Obey
Olver
Ortiz
Oxley
Packard
Parker
Pascrell
Paul
Paxon
Pease
Pelosi
Peterson (MN)
Peterson (PA)
Petri
Pickett
Pitts
Pombo
Pomeroy
Porter
Poshard
Price (NC)
Quinn
Radanovich
Rahall
Ramstad
Rangel
Redmond
Regula
Reyes
Riggs
Rivers
Rodriguez
Rogers
Roybal-Allard
Ryun
Sabo
Sanchez
Sanders
Sandlin
Sawyer
Saxton
Schaefer, Dan
Schumer
Scott
Sensenbrenner
Serrano
Sessions
Shadegg
Shaw
Shays
Shimkus
Shuster
Sisisky
Skaggs
Skeen
Skelton
Smith (MI)
Smith (NJ)
Smith (OR)
Smith (TX)
Smith, Adam
Smith, Linda
Snowbarger
Snyder
Solomon
Souder
Spence
Spratt
Stabenow
Stark
Stearns
Stenholm
Strickland
Stump
Stupak
Sununu
Talent
Tanner
Tauscher
Tauzin
Taylor (MS)
Taylor (NC)
Thomas
Thornberry
Thune
Thurman
Tierney
Traficant
Turner
Upton
Velazquez
Vento
Visclosky
Walsh
Wamp
Watkins
Watts (OK)
Waxman
Weldon (FL)
Weldon (PA)
Weygand
White
Whitfield
Wise
Wolf
Woolsey
Young (AK)
Young (FL)

ANSWERED ''PRESENT''—4

Cardin
English
Hoyer
Kucinich

NOT VOTING—10

Cubin
Gillmor
Gonzalez
Klug
McDermott
Pickering
Riley
Roukema
Schiff
Yates

The SPEAKER pro tempore, Mr. PETRI, announced that two-thirds of the Members present had not voted in the affirmative.

So, less than two-thirds of the Members present having voted in favor thereof, the rules were not suspended and said concurrent resolution, as amended, was not agreed to.

¶130.25 H. CON. RES. 139—UNFINISHED BUSINESS

The SPEAKER pro tempore, Mr. PETRI, pursuant to clause 5, rule I, announced the further unfinished business to be the motion to suspend the rules and agree to concurrent resolution (H. Con. Res. 139) expressing the sense of Congress that the United States Government should fully participate in EXPO 2000 in the year 2000, in Hanover Germany, and should encourage the academic community and the private sector in the United States to support this worthwhile undertaking; as amended.

The question being put,

Will the House suspend the rules and agree to said concurrent resolution as amended?

The vote was taken by electronic device.

It was decided in the affirmative { Yeas ..... 415 / Nays 2

¶130.26 [Roll No. 626]

YEAS—415

Abercrombie	Deutsch	Jackson (IL)
Ackerman	Diaz-Balart	Jefferson
Aderholt	Dickey	Jenkins
Allen	Dicks	John
Andrews	Dingell	Johnson (CT)
Archer	Dixon	Johnson (WI)
Bachus	Doggett	Johnson, E. B.
Baesler	Dooley	Johnson, Sam
Baker	Doolittle	Jones
Baldacci	Doyle	Kanjorski
Ballenger	Dreier	Kaptur
Barcia	Duncan	Kasich
Barrett (NE)	Dunn	Kelly
Barrett (WI)	Ehlers	Kennedy (MA)
Bartlett	Ehrlich	Kennedy (RI)
Barton	Engel	Kennelly
Bass	English	Kildee
Bateman	Ensign	Kilpatrick
Becerra	Eshoo	Kim
Bentsen	Etheridge	Kind (WI)
Bereuter	Evans	King (NY)
Berman	Everett	Kingston
Berry	Ewing	Kleczka
Bilbray	Farr	Klink
Bilirakis	Fattah	Knollenberg
Bishop	Fawell	Kolbe
Blagojevich	Fazio	Kucinich
Bliley	Filner	LaFalce
Blumenauer	Flake	LaHood
Blunt	Foglietta	Lampson
Boehlert	Foley	Lantos
Boehner	Forbes	Largent
Bonilla	Ford	Latham
Bonior	Fossella	LaTourette
Bono	Fowler	Lazio
Borski	Fox	Leach
Boswell	Frank (MA)	Levin
Boucher	Franks (NJ)	Lewis (CA)
Boyd	Frelinghuysen	Lewis (GA)
Brady	Frost	Lewis (KY)
Brown (CA)	Furse	Linder
Brown (FL)	Gallegly	Lipinski
Brown (OH)	Ganske	Livingston
Bryant	Gejdenson	LoBiondo
Bunning	Gekas	Lofgren
Burr	Gephardt	Lowey
Burton	Gibbons	Lucas
Buyer	Gilchrest	Luther
Callahan	Gilman	Maloney (CT)
Calvert	Goode	Maloney (NY)
Camp	Goodlatte	Manton
Campbell	Goodling	Manzullo
Canady	Gordon	Markey
Cannon	Goss	Martinez
Cardin	Graham	Mascara
Carson	Granger	Matsui
Castle	Green	McCarthy (MO)
Chabot	Greenwood	McCarthy (NY)
Chambliss	Gutierrez	McCollum
Chenoweth	Gutknecht	McCrery
Christensen	Hall (OH)	McDade
Clay	Hall (TX)	McGovern
Clayton	Hamilton	McHale
Clement	Hansen	McHugh
Clyburn	Harman	McInnis
Coble	Hastert	McIntosh
Coburn	Hastings (FL)	McIntyre
Collins	Hastings (WA)	McKeon
Combest	Hayworth	McKinney
Condit	Hefley	McNulty
Conyers	Hefner	Meehan
Cook	Herger	Meek
Cooksey	Hill	Menendez
Costello	Hilleary	Metcalf
Cox	Hilliard	Mica
Coyne	Hinchey	Millender-McDonald
Cramer	Hinojosa	Miller (CA)
Crane	Hobson	Miller (FL)
Crapo	Hoekstra	Minge
Cummings	Holden	Mink
Cunningham	Hooley	Moakley
Danner	Horn	Mollohan
Davis (FL)	Hostettler	Moran (KS)
Davis (IL)	Houghton	Moran (VA)
Davis (VA)	Hoyer	Morella
Deal	Hulshof	Murtha
DeFazio	Hunter	Myrick
DeGette	Hutchinson	Nadler
Delahunt	Hyde	Neal
DeLauro	Inglis	Nethercutt
Dellums	Istook	Neumann
Ney	Ros-Lehtinen	Stokes
Northup	Rothman	Strickland
Norwood	Roybal-Allard	Stump
Nussle	Royce	Stupak
Oberstar	Rush	Sununu
Obey	Ryun	Talent
Olver	Sabo	Tanner
Ortiz	Salmon	Tauscher
Owens	Sanchez	Tauzin
Oxley	Sanders	Taylor (MS)
Packard	Sandlin	Taylor (NC)
Pallone	Sanford	Thomas
Pappas	Sawyer	Thompson
Parker	Saxton	Thornberry
Pascrell	Scarborough	Thune
Pastor	Schaefer, Dan	Thurman
Paul	Schaffer, Bob	Tiahrt
Paxon	Schumer	Tierney
Payne	Scott	Torres
Pease	Sensenbrenner	Towns
Pelosi	Serrano	Traficant
Peterson (MN)	Sessions	Turner
Peterson (PA)	Shadegg	Upton
Petri	Shaw	Velazquez
Pickering	Shays	Vento
Pickett	Sherman	Visclosky
Pitts	Shimkus	Walsh
Pombo	Shuster	Wamp
Pomeroy	Sisisky	Waters
Porter	Skaggs	Watkins
Poshard	Skeen	Watt (NC)
Price (NC)	Skelton	Watts (OK)
Pryce (OH)	Slaughter	Waxman
Quinn	Smith (MI)	Weldon (FL)
Radanovich	Smith (NJ)	Weldon (PA)
Rahall	Smith (OR)	Weller
Ramstad	Smith (TX)	Wexler
Rangel	Smith, Adam	Weygand
Redmond	Snowbarger	White
Regula	Snyder	Wicker
Reyes	Solomon	Wise
Riggs	Souder	Wolf
Rivers	Spence	Woolsey
Rodriguez	Spratt	Wynn
Roemer	Stabenow	Young (AK)
Rogan	Stark	Young (FL)
Rogers	Stearns	

NAYS—2

Barr	Jackson-Lee (TX)

NOT VOTING—16

Armey	Gonzalez	Schiff
Cubin	Klug	Smith, Linda
DeLay	McDermott	Whitfield
Edwards	Portman	Yates
Emerson	Riley	
Gillmor	Roukema	

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said concurrent resolution, as amended, was agreed to, as amended, was passed.

By unanimous consent, the title was amended so as to read: ''A concurrent resolution expressing the sense of Congress that the United States should fully participate in EXPO 2000 in the year 2000, in Hanover, Germany, and should encourage the academic community and the private sector in the United States to support this worthwhile undertaking .''.

A motion to reconsider the vote whereby the rules were suspended and said concurrent resolution, as amended, was agreed to and the title was amended was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.27 SUBMISSION OF CONFERENCE REPORT—S. 830

Mr. BLILEY submitted a conference report (Rept. No. 105–399) on the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes; together with a statement thereon, for printing in the Record under the rule.

¶130.28 FURTHER CONTINUING APPROPRIATIONS

On motion of Mr. LIVINGSTON, by unanimous consent, the Committee on Appropriations was discharged from further consideration of the joint resolution (H.J. Res. 104) making further continuing appropriations for the fiscal year 1998, and for other purposes.

When said joint resolution was considered, read twice, and was ordered to be read a third time, was read a third time by title, and passed.

A motion to reconsider the vote whereby said joint resolution was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said joint resolution.

¶130.29 FDA MODERNIZATION AND ACCOUNTABILITY

Mr. BLILEY moved to suspend the rules and agree to the following conference report (Rept. No. 105–399):

The Committee of conference on the disagreeing votes of the two Houses on the amendments of the House to the bill (S. 830) to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House to the text of the bill and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE; REFERENCES; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Food and Drug Administration Modernization Act of 1997''.

(b) REFERENCES.—Except as otherwise specified, whenever in this Act an amendment or repeal is expressed in terms of an amendment to or a repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(c) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. DEFINITIONS.

In this Act, the terms ''drug'', ''device'', ''food'', and ''dietary supplement'' have the meaning given such terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

TITLE I—IMPROVING REGULATION OF DRUGS

Subtitle A—Fees Relating to Drugs

SEC. 101. FINDINGS.

Congress finds that—

(1) prompt approval of safe and effective new drugs and other therapies is critical to the improvement of the public health so that patients may enjoy the benefits provided by these therapies to treat and prevent illness and disease;

(2) the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of human drug applications;

(3) the provisions added by the Prescription Drug User Fee Act of 1992 have been successful in substantially reducing review times for human drug applications and should be—

(A) reauthorized for an additional 5 years, with certain technical improvements; and

(B) carried out by the Food and Drug Administration with new commitments to implement more ambitious and comprehensive improvements in regulatory processes of the Food and Drug Administration; and

(4) the fees authorized by amendments made in this subtitle will be dedicated toward expediting the drug development process and the review of human drug applications as set forth in the goals identified, for purposes of part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the chairman of the Committee on Commerce of the House of Representatives and the chairman of the Committee on Labor and Human Resources of the Senate, as set forth in the Congressional Record.

SEC. 102. DEFINITIONS.

Section 735 (21 U.S.C. 379g) is amended—

(1) in the second sentence of paragraph (1)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include an application for a licensure of a biological product for further manufacturing use only, and does not include an application or supplement submitted by a State or Federal Government entity for a drug that is not distributed commercially. Such term does include an application for licensure, as described in subparagraph (D), of a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(2) in the second sentence of paragraph (3)—

(A) by striking ''Service Act, and'' and inserting ''Service Act,''; and

(B) by striking ''September 1, 1992.'' and inserting the following: ''September 1, 1992, does not include a biological product that is licensed for further manufacturing use only, and does not include a drug that is not distributed commercially and is the subject of an application or supplement submitted by a State or Federal Government entity. Such term does include a large volume biological product intended for single dose injection for intravenous use or infusion.'';

(3) in paragraph (4), by striking ''without'' and inserting ''without substantial'';

(4) by amending the first sentence of paragraph (5) to read as follows:

''(5) The term 'prescription drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within five miles of each other and at which one or more prescription drug products are manufactured in final dosage form.'';

(5) in paragraph (7)(A)—

(A) by striking ''employees under contract'' and all that follows through ''Administration,'' the second time it occurs and inserting ''contractors of the Food and Drug Administration,''; and

(B) by striking ''and committees,'' and inserting ''and committees and to contracts with such contractors,'';

(6) in paragraph (8)—

(A) in subparagraph (A)—

(i) by striking ''August of'' and inserting ''April of''; and

(ii) by striking ''August 1992'' and inserting ''April 1997''; and

(B) in subparagraph (B)—

(i) by striking ''section 254(d)'' and inserting ''section 254(c)'';

(ii) by striking ''1992'' and inserting ''1997''; and

(iii) by striking ''102d Congress, 2d Session'' and inserting ''105th Congress, 1st Session''; and

(7) by adding at the end the following:

''(9) The term 'affiliate' means a business entity that has a relationship with a second business entity if, directly or indirectly—

''(A) one business entity controls, or has the power to control, the other business entity; or

''(B) a third party controls, or has power to control, both of the business entities.''.

SEC. 103. AUTHORITY TO ASSESS AND USE DRUG FEES.

(a) TYPES OF FEES.—Section 736(a) (21 U.S.C. 379h(a)) is amended—

(1) by striking ''Beginning in fiscal year 1993'' and inserting ''Beginning in fiscal year 1998'';

(2) in paragraph (1)—

(A) by striking subparagraph (B) and inserting the following:

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the application or supplement.'';

(B) in subparagraph (D)—

(i) in the subparagraph heading, by striking ''NOT ACCEPTED'' and inserting ''REFUSED'';

(ii) by striking ''50 percent'' and inserting ''75 percent'';

(iii) by striking ''subparagraph (B)(i)'' and inserting ''subparagraph (B)''; and

(iv) by striking ''not accepted'' and inserting ''refused''; and

(C) by adding at the end the following:

''(E) EXCEPTION FOR DESIGNATED ORPHAN DRUG OR INDICATION.—A human drug application for a prescription drug product that has been designated as a drug for a rare disease or condition pursuant to section 526 shall not be subject to a fee under subparagraph (A), unless the human drug application includes

an indication for other than a rare disease or condition. A supplement proposing to include a new indication for a rare disease or condition in a human drug application shall not be subject to a fee under subparagraph (A), if the drug has been designated pursuant to section 526 as a drug for a rare disease or condition with regard to the indication proposed in such supplement.

''(F) EXCEPTION FOR SUPPLEMENTS FOR PEDIATRIC INDICATIONS.—A supplement to a human drug application proposing to include a new indication for use in pediatric populations shall not be assessed a fee under subparagraph (A).

''(G) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an application or supplement is withdrawn after the application or supplement was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee under this subparagraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.'';

(3) by striking paragraph (2) and inserting the following:

''(2) PRESCRIPTION DRUG ESTABLISHMENT FEE.—

''(A) IN GENERAL.—Except as provided in subparagraph (B), each person that—

''(i) is named as the applicant in a human drug application; and

''(ii) after September 1, 1992, had pending before the Secretary a human drug application or supplement,

shall be assessed an annual fee established in subsection (b) for each prescription drug establishment listed in its approved human drug application as an establishment that manufactures the prescription drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the prescription drug product named in the application is assessed a fee under paragraph (3) unless the prescription drug establishment listed in the application does not engage in the manufacture of the prescription drug product during the fiscal year. The establishment fee shall be payable on or before January 31 of each year. Each such establishment shall be assessed only one fee per establishment, notwithstanding the number of prescription drug products manufactured at the establishment. In the event an establishment is listed in a human drug application by more than one applicant, the establishment fee for the fiscal year shall be divided equally and assessed among the applicants whose prescription drug products are manufactured by the establishment during the fiscal year and assessed product fees under paragraph (3).

''(B) EXCEPTION.—If, during the fiscal year, an applicant initiates or causes to be initiated the manufacture of a prescription drug product at an establishment listed in its human drug application—

''(i) that did not manufacture the product in the previous fiscal year; and

''(ii) for which the full establishment fee has been assessed in the fiscal year at a time before manufacture of the prescription drug product was begun;

the applicant will not be assessed a share of the establishment fee for the fiscal year in which the manufacture of the product began.''; and

(4) in paragraph (3)—

(A) in subparagraph (A)—

(i) in clause (i), by striking ''is listed'' and inserting ''has been submitted for listing''; and

(ii) by striking ''Such fee shall be payable'' and all that follows through ''section 510.'' and inserting the following: ''Such fee shall be payable for the fiscal year in which the product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each product for a fiscal year in which the fee is payable.''; and

(B) in subparagraph (B), by striking ''505(j).'' and inserting the following: ''505(j), under an abbreviated application filed under section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997), or under an abbreviated new drug application pursuant to regulations in effect prior to the implementation of the Drug Price Competition and Patent Term Restoration Act of 1984.''.

(b) FEE AMOUNTS.—Section 736(b) (21 U.S.C. 379h(b)) is amended to read as follows:

''(b) FEE AMOUNTS.—Except as provided in subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be determined and assessed as follows:

''(1) APPLICATION AND SUPPLEMENT FEES.—

''(A) FULL FEES.—The application fee under subsection (a)(1)(A)(i) shall be $250,704 in fiscal year 1998, $256,338 in each of fiscal years 1999 and 2000, $267,606 in fiscal year 2001, and $258,451 in fiscal year 2002.

''(B) OTHER FEES.—The fee under subsection (a)(1)(A)(ii) shall be $125,352 in fiscal year 1998, $128,169 in each of fiscal years 1999 and 2000, $133,803 in fiscal year 2001, and $129,226 in fiscal year 2002.

''(2) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(2) shall be $35,600,000 in fiscal year 1998, $36,400,000 in each of fiscal years 1999 and 2000, $38,000,000 in fiscal year 2001, and $36,700,000 in fiscal year 2002.

''(3) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(3) in a fiscal year shall be equal to the total fee revenues collected in establishment fees under subsection (a)(2) in that fiscal year.''.

(c) INCREASES AND ADJUSTMENTS.—Section 736(c) (21 U.S.C. 379h(c)) is amended—

(1) in the subsection heading, by striking ''INCREASES AND'';

(2) in paragraph (1)—

(A) by striking ''(1) REVENUE'' and all that follows through ''increased by the Secretary'' and inserting the following: ''(1) INFLATION ADJUSTMENT.—The fees and total fee revenues established in subsection (b) shall be adjusted by the Secretary'';

(B) in subparagraph (A), by striking ''increase'' and inserting ''change'';

(C) in subparagraph (B), by striking ''increase'' and inserting ''change''; and

(D) by adding at the end the following flush sentence:

''The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 1997 under this subsection.'';

(3) in paragraph (2), by striking ''October 1, 1992,'' and all that follows through ''such schedule.'' and inserting the following: ''September 30, 1997, adjust the establishment and product fees described in subsection (b) for the fiscal year in which the adjustment occurs so that the revenues collected from each of the categories of fees described in paragraphs (2) and (3) of subsection (b) shall be set to be equal to the revenues collected from the category of application and supplement fees described in paragraph (1) of subsection (b).''; and

(4) in paragraph (3), by striking ''paragraph (2)'' and inserting ''this subsection''.

(d) FEE WAIVER OR REDUCTION.—Section 736(d) (21 U.S.C. 379h(d)) is amended—

(1) by redesignating paragraphs (1), (2), (3), and (4) as subparagraphs (A), (B), (C), and (D), respectively and indenting appropriately;

(2) by striking ''The Secretary shall grant a'' and all that follows through ''finds that—'' and inserting the following:

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of one or more fees assessed under subsection (a) where the Secretary finds that—'';

(3) in subparagraph (C) (as so redesignated in paragraph (1)), by striking '', or'' and inserting a comma;

(4) in subparagraph (D) (as so redesignated in paragraph (1)), by striking the period and inserting '', or'';

(5) by inserting after subparagraph (D) (as so redesignated in paragraph (1)) the following:

''(E) the applicant involved is a small business submitting its first human drug application to the Secretary for review.''; and

(6) by striking ''In making the finding in paragraph (3),'' and all that follows through ''standard costs.'' and inserting the following:

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(C), the Secretary may use standard costs.

''(3) RULES RELATING TO SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first human drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay—

''(i) application fees for all subsequent human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business; and

''(ii) all supplement fees for all supplements to human drug applications submitted to the Secretary for review in the same manner as an entity that does not qualify as a small business.''.

(e) ASSESSMENT OF FEES.—Section 736(f)(1) (21 U.S.C. 379h(f)(1)) is amended—

(1) by striking ''fiscal year 1993'' and inserting ''fiscal year 1997''; and

(2) by striking ''fiscal year 1992'' and inserting ''fiscal year 1997 (excluding the amount of fees appropriated for such fiscal year)''.

(f) CREDITING AND AVAILABILITY OF FEES.—Section 736(g) (21 U.S.C. 379h(g)) is amended—

(1) in paragraph (1), by adding at the end the following: ''Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salaries and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of human drug applications.'';

(2) in paragraph (2)—

(A) in subparagraph (A), by striking ''Acts'' and inserting ''Acts, or otherwise made available for obligation,''; and

(B) in subparagraph (B), by striking ''over such costs for fiscal year 1992'' and inserting ''over such costs, excluding costs paid from fees collected under this section, for fiscal year 1997''; and

(3) by striking paragraph (3) and inserting the following:

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $106,800,000 for fiscal year 1998;

''(B) $109,200,000 for fiscal year 1999;

''(C) $109,200,000 for fiscal year 2000;

''(D) $114,000,000 for fiscal year 2001; and

''(E) $110,100,000 for fiscal year 2002,

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by application, supplement, establishment, and product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriation Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.''.

(g) REQUIREMENT FOR WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—Section 736 (21 U.S.C. 379h) is amended—

(1) by redesignating subsection (i) as subsection (j); and

(2) by inserting after subsection (h) the following:

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.''.

(h) SPECIAL RULE FOR WAIVERS AND REFUNDS.—Any requests for waivers or refunds for fees assessed under section 736 of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 379h) prior to the date of enactment of this Act shall be submitted in writing to the Secretary of Health and Human Services within 1 year after the date of enactment of this Act. Any requests for waivers or refunds pertaining to a fee for a human drug application or supplement accepted for filing prior to October 1, 1997 or to a product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998, shall be evaluated according to the terms of the Prescription Drug User Fee Act of 1992 (as in effect on September 30, 1997) and part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (as in effect on September 30, 1997). The term ''person'' in such Acts shall continue to include an affiliate thereof.

SEC. 104. ANNUAL REPORTS.

(a) PERFORMANCE REPORT.—Beginning with fiscal year 1998, not later than 60 days after the end of each fiscal year during which fees are collected under part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g et seq.), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 101(4) during such fiscal year and the future plans of the Food and Drug Administration for meeting the goals.

(b) FISCAL REPORT.—Beginning with fiscal year 1998, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary of Health and Human Services shall prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 105. SAVINGS.

Notwithstanding section 105 of the Prescription Drug User Fee Act of 1992, the Secretary shall retain the authority to assess and collect any fee required by part 2 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act for a human drug application or supplement accepted for filing prior to October 1, 1997, and to assess and collect any product or establishment fee required by such Act for a fiscal year prior to fiscal year 1998.

SEC. 106. EFFECTIVE DATE.

The amendments made by this subtitle shall take effect October 1, 1997.

SEC. 107. TERMINATION OF EFFECTIVENESS.

The amendments made by sections 102 and 103 cease to be effective October 1, 2002, and section 104 ceases to be effective 120 days after such date.

Subtitle B—Other Improvements

SEC. 111. PEDIATRIC STUDIES OF DRUGS.

Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after section 505 the following:

''SEC. 505A. PEDIATRIC STUDIES OF DRUGS.

''(a) MARKET EXCLUSIVITY FOR NEW DRUGS.—If, prior to approval of an application that is submitted under section 505(b)(1), the Secretary determines that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), and such studies are completed within any such timeframe and the reports thereof submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

''(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

''(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsections (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(b) SECRETARY TO DEVELOP LIST OF DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY BE BENEFICIAL.—Not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with experts in pediatric research shall develop, prioritize, and publish an initial list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population. The Secretary shall annually update the list.

''(c) MARKET EXCLUSIVITY FOR ALREADY-MARKETED DRUGS.—If the Secretary makes a written request to the holder of an approved application under section 505(b)(1) for pediatric studies (which shall include a timeframe for completing such studies) concerning a drug identified in the list described in subsection (b), the holder agrees to the request, the studies are completed within any such timeframe, and the reports thereof are submitted in accordance with subsection (d)(2) or accepted in accordance with subsection (d)(3)—

''(1)(A)(i) the period referred to in subsection (c)(3)(D)(ii) of section 505, and in subsection (j)(4)(D)(ii) of such section, is deemed to be five years and six months rather than five years, and the references in subsections (c)(3)(D)(ii) and (j)(4)(D)(ii) of such section to four years, to forty-eight months, and to seven and one-half years are deemed to be four and one-half years, fifty-four months, and eight years, respectively; or

''(ii) the period referred to in clauses (iii) and (iv) of subsection (c)(3)(D) of such section, and in clauses (iii) and (iv) of subsection (j)(4)(D) of such section, is deemed to be three years and six months rather than three years; and

''(B) if the drug is designated under section 526 for a rare disease or condition, the period referred to in section 527(a) is deemed to be seven years and six months rather than seven years; and

''(2)(A) if the drug is the subject of—

''(i) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(ii) or (j)(2)(A)(vii)(II) of section 505 and for which pediatric studies were submitted prior to the expiration of the patent (including any patent extensions); or

''(ii) a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iii) or (j)(2)(A)(vii)(III) of section 505,

the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions); or

''(B) if the drug is the subject of a listed patent for which a certification has been submitted under subsection (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505, and in the patent infringement litigation resulting from the certification the court determines that the patent is valid and would be infringed, the period during which an application may not be approved under section 505(c)(3) or section 505(j)(4)(B) shall be extended by a period of six months after the date the patent expires (including any patent extensions).

''(d) CONDUCT OF PEDIATRIC STUDIES.—

''(1) AGREEMENT FOR STUDIES.—The Secretary may, pursuant to a written request from the Secretary under subsection (a) or (c), after consultation with—

''(A) the sponsor of an application for an investigational new drug under section 505(i);

''(B) the sponsor of an application for a new drug under section 505(b)(1); or

''(C) the holder of an approved application for a drug under section 505(b)(1),

agree with the sponsor or holder for the conduct of pediatric studies for such drug. Such agreement shall be in writing and shall include a timeframe for such studies.

''(2) WRITTEN PROTOCOLS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary agree upon written protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied upon the completion of the studies and submission of the reports thereof in accordance with the original written request and the written agreement referred to in paragraph (1). Not later than 60 days after the submission of the report of the studies, the Secretary shall determine if such studies were or were not conducted in accordance with the original written request and the written agreement and reported in accordance with the requirements of the Secretary for filing and so notify the sponsor or holder.

''(3) OTHER METHODS TO MEET THE STUDIES REQUIREMENT.—If the sponsor or holder and the Secretary have not agreed in writing on the protocols for the studies, the studies requirement of subsection (a) or (c) is satisfied when such studies have been completed and the reports accepted by the Secretary. Not later than 90 days after the submission of the reports of the studies, the Secretary shall accept or reject such reports and so notify the sponsor or holder. The Secretary's only responsibility in accepting or rejecting the reports shall be to determine, within the 90 days, whether the studies fairly respond to the written request, have been conducted in accordance with commonly accepted scientific principles and protocols, and have been reported in accordance with the requirements of the Secretary for filing.

''(e) DELAY OF EFFECTIVE DATE FOR CERTAIN APPLICATION.—If the Secretary determines that the acceptance or approval of an application under section 505(b)(2) or 505(j) for a new drug may occur after submission of reports of pediatric studies under this section, which were submitted prior to the expiration of the patent (including any patent extension) or the applicable period under clauses (ii) through (iv) of section 505(c)(3)(D) or clauses (ii) through (iv) of section 505(j)(4)(D), but before the Secretary has determined whether the requirements of subsection (d) have been satisfied, the Secretary shall delay the acceptance or approval under section 505(b)(2) or 505(j) until the determination under subsection (d) is made, but any such delay shall not exceed 90 days. In the event that requirements of this section are satisfied, the applicable six-month period under subsection (a) or (c) shall be deemed to have been running during the period of delay.

''(f) NOTICE OF DETERMINATIONS ON STUDIES REQUIREMENT.—The Secretary shall publish a notice of any determination that the requirements of subsection (d) have been met and that submissions and approvals under subsection (b)(2) or (j) of section 505 for a drug will be subject to the provisions of this section.

''(g) DEFINITIONS.—As used in this section, the term 'pediatric studies' or 'studies' means at least one clinical investigation (that, at the Secretary's discretion, may include pharmacokinetic studies) in pediatric age groups in which a drug is anticipated to be used.

''(h) LIMITATIONS.—A drug to which the six-month period under subsection (a) or (b) has already been applied—

''(1) may receive an additional six-month period under subsection (c)(1)(A)(ii) for a supplemental application if all other requirements under this section are satisfied, except that such a drug may not receive any additional such period under subsection (c)(2); and

''(2) may not receive any additional such period under subsection (c)(1)(B).

''(i) RELATIONSHIP TO REGULATIONS.—Notwithstanding any other provision of law, if any pediatric study is required pursuant to regulations promulgated by the Secretary and such study meets the completeness, timeliness, and other requirements of this section, such study shall be deemed to satisfy the requirement for market exclusivity pursuant to this section.

''(j) SUNSET.—A drug may not receive any six-month period under subsection (a) or (c) unless the application for the drug under section 505(b)(1) is submitted on or before January 1, 2002. After January 1, 2002, a drug shall receive a six-month period under subsection (c) if—

''(1) the drug was in commercial distribution as of the date of enactment of the Food and Drug Administration Modernization Act of 1997;

''(2) the drug was included by the Secretary on the list under subsection (b) as of January 1, 2002;

''(3) the Secretary determines that there is a continuing need for information relating to the use of the drug in the pediatric population and that the drug may provide health benefits in that population; and

''(4) all requirements of this section are met.

''(k) REPORT.—The Secretary shall conduct a study and report to Congress not later than January 1, 2001, based on the experience under the program established under this section. The study and report shall examine all relevant issues, including—

''(1) the effectiveness of the program in improving information about important pediatric uses for approved drugs;

''(2) the adequacy of the incentive provided under this section;

''(3) the economic impact of the program on taxpayers and consumers, including the impact of the lack of lower cost generic drugs on patients, including on lower income patients; and

''(4) any suggestions for modification that the Secretary determines to be appropriate.''.

SEC. 112. EXPEDITING STUDY AND APPROVAL OF FAST TRACK DRUGS.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.), as amended by section 125, is amended by inserting before section 508 the following:

''SEC. 506. FAST TRACK PRODUCTS.

''(a) DESIGNATION OF DRUG AS A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary shall, at the request of the sponsor of a new drug, facilitate the development and expedite the review of such drug if it is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for such a condition. (In this section, such a drug is referred to as a 'fast track product'.)

''(2) REQUEST FOR DESIGNATION.—The sponsor of a new drug may request the Secretary to designate the drug as a fast track product. A request for the designation may be made concurrently with, or at any time after, submission of an application for the investigation of the drug under section 505(i) or section 351(a)(3) of the Public Health Service Act.

''(3) DESIGNATION.—Within 60 calendar days after the receipt of a request under paragraph (2), the Secretary shall determine whether the drug that is the subject of the request meets the criteria described in paragraph (1). If the Secretary finds that the drug meets the criteria, the Secretary shall designate the drug as a fast track product and shall take such actions as are appropriate to expedite the development and review of the application for approval of such product.

''(b) APPROVAL OF APPLICATION FOR A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—The Secretary may approve an application for approval of a fast track product under section 505(c) or section 351 of the Public Health Service Act upon a determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.

''(2) LIMITATION.—Approval of a fast track product under this subsection may be subject to the requirements—

''(A) that the sponsor conduct appropriate post-approval studies to validate the surrogate endpoint or otherwise confirm the effect on the clinical endpoint; and

''(B) that the sponsor submit copies of all promotional materials related to the fast track product during the preapproval review period and, following approval and for such period thereafter as the Secretary determines to be appropriate, at least 30 days prior to dissemination of the materials.

''(3) EXPEDITED WITHDRAWAL OF APPROVAL.—The Secretary may withdraw approval of a fast track product using expedited procedures (as prescribed by the Secretary in regulations which shall include an opportunity for an informal hearing) if—

''(A) the sponsor fails to conduct any required post-approval study of the fast track drug with due diligence;

''(B) a post-approval study of the fast track product fails to verify clinical benefit of the product;

''(C) other evidence demonstrates that the fast track product is not safe or effective under the conditions of use; or

''(D) the sponsor disseminates false or misleading promotional materials with respect to the product.

''(c) REVIEW OF INCOMPLETE APPLICATIONS FOR APPROVAL OF A FAST TRACK PRODUCT.—

''(1) IN GENERAL.—If the Secretary determines, after preliminary evaluation of clinical data submitted by the sponsor, that a fast track product may be effective, the Secretary shall evaluate for filing, and may commence review of portions of, an application for the approval of the product before the sponsor submits a complete application. The Secretary shall commence such review only if the applicant—

''(A) provides a schedule for submission of information necessary to make the application complete; and

''(B) pays any fee that may be required under section 736.

''(2) EXCEPTION.—Any time period for review of human drug applications that has been agreed to by the Secretary and that has been set forth in goals identified in letters of the Secretary (relating to the use of fees collected under section 736 to expedite the drug development process and the review of human drug applications) shall not apply to an application submitted under paragraph (1) until the date on which the application is complete.

''(d) AWARENESS EFFORTS.—The Secretary shall—

''(1) develop and disseminate to physicians, patient organizations, pharmaceutical and biotechnology companies, and other appropriate persons a description of the provisions of this section applicable to fast track products; and

''(2) establish a program to encourage the development of surrogate endpoints that are reasonably likely to predict clinical benefit for serious or life-threatening conditions for

which there exist significant unmet medical needs.''.

(b) GUIDANCE.—Within 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance for fast track products (as defined in section 506(a)(1) of the Federal Food, Drug, and Cosmetic Act) that describes the policies and procedures that pertain to section 506 of such Act.

SEC. 113. INFORMATION PROGRAM ON CLINICAL TRIALS FOR SERIOUS OR LIFE-THREATENING DISEASES.

(a) IN GENERAL.—Section 402 of the Public Health Service Act (42 U.S.C. 282) is amended—

(1) by redesignating subsections (j) and (k) as subsections (k) and (l), respectively; and

(2) by inserting after subsection (i) the following:

''(j)(1)(A) The Secretary, acting through the Director of NIH, shall establish, maintain, and operate a data bank of information on clinical trials for drugs for serious or life-threatening diseases and conditions (in this subsection referred to as the 'data bank'). The activities of the data bank shall be integrated and coordinated with related activities of other agencies of the Department of Health and Human Services, and to the extent practicable, coordinated with other data banks containing similar information.

''(B) The Secretary shall establish the data bank after consultation with the Commissioner of Food and Drugs, the directors of the appropriate agencies of the National Institutes of Health (including the National Library of Medicine), and the Director of the Centers for Disease Control and Prevention.

''(2) In carrying out paragraph (1), the Secretary shall collect, catalog, store, and disseminate the information described in such paragraph. The Secretary shall disseminate such information through information systems, which shall include toll-free telephone communications, available to individuals with serious or life-threatening diseases and conditions, to other members of the public, to health care providers, and to researchers.

''(3) The data bank shall include the following:

''(A) A registry of clinical trials (whether federally or privately funded) of experimental treatments for serious or life-threatening diseases and conditions under regulations promulgated pursuant to section 505(i) of the Federal Food, Drug, and Cosmetic Act, which provides a description of the purpose of each experimental drug, either with the consent of the protocol sponsor, or when a trial to test effectiveness begins. Information provided shall consist of eligibility criteria for participation in the clinical trials, a description of the location of trial sites, and a point of contact for those wanting to enroll in the trial, and shall be in a form that can be readily understood by members of the public. Such information shall be forwarded to the data bank by the sponsor of the trial not later than 21 days after the approval of the protocol.

''(B) Information pertaining to experimental treatments for serious or life-threatening diseases and conditions that may be available—

''(i) under a treatment investigational new drug application that has been submitted to the Secretary under section 561(c) of the Federal Food, Drug, and Cosmetic Act; or

''(ii) as a Group C cancer drug (as defined by the National Cancer Institute).

The data bank may also include information pertaining to the results of clinical trials of such treatments, with the consent of the sponsor, including information concerning potential toxicities or adverse effects associated with the use or administration of such experimental treatments.

''(4) The data bank shall not include information relating to an investigation if the sponsor has provided a detailed certification to the Secretary that disclosure of such information would substantially interfere with the timely enrollment of subjects in the investigation, unless the Secretary, after the receipt of the certification, provides the sponsor with a detailed written determination that such disclosure would not substantially interfere with such enrollment.

''(5) For the purpose of carrying out this subsection, there are authorized to be appropriated such sums as may be necessary. Fees collected under section 736 of the Federal Food, Drug, and Cosmetic Act shall not be used in carrying out this subsection.''.

(b) COLLABORATION AND REPORT.—

(1) IN GENERAL.—The Secretary of Health and Human Services, the Director of the National Institutes of Health, and the Commissioner of Food and Drugs shall collaborate to determine the feasibility of including device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act.

(2) REPORT.—Not later than two years after the date of enactment of this section, the Secretary of Health and Human Services shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report—

(A) of the public health need, if any, for inclusion of device investigations within the scope of the data bank under section 402(j) of the Public Health Service Act;

(B) on the adverse impact, if any, on device innovation and research in the United States if information relating to such device investigations is required to be publicly disclosed; and

(C) on such other issues relating to such section 402(j) as the Secretary determines to be appropriate.

SEC. 114. HEALTH CARE ECONOMIC INFORMATION.

(a) IN GENERAL.—Section 502(a) (21 U.S.C. 352(a)) is amended by adding at the end the following: ''Health care economic information provided to a formulary committee, or other similar entity, in the course of the committee or the entity carrying out its responsibilities for the selection of drugs for managed care or other similar organizations, shall not be considered to be false or misleading under this paragraph if the health care economic information directly relates to an indication approved under section 505 or under section 351(a) of the Public Health Service Act for such drug and is based on competent and reliable scientific evidence. The requirements set forth in section 505(a) or in section 351(a) of the Public Health Service Act shall not apply to health care economic information provided to such a committee or entity in accordance with this paragraph. Information that is relevant to the substantiation of the health care economic information presented pursuant to this paragraph shall be made available to the Secretary upon request. In this paragraph, the term 'health care economic information' means any analysis that identifies, measures, or compares the economic consequences, including the costs of the represented health outcomes, of the use of a drug to the use of another drug, to another health care intervention, or to no intervention.''.

(b) STUDY AND REPORT.—The Comptroller General of the United States shall conduct a study of the implementation of the provisions added by the amendment made by subsection (a). Not later than 4 years and 6 months after the date of enactment of this Act, the Comptroller General of the United States shall prepare and submit to Congress a report containing the findings of the study.

SEC. 115. CLINICAL INVESTIGATIONS.

(a) CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.—Section 505(d) (21 U.S.C. 355(d)) is amended by adding at the end the following: ''If the Secretary determines, based on relevant science, that data from one adequate and well-controlled clinical investigation and confirmatory evidence (obtained prior to or after such investigation) are sufficient to establish effectiveness, the Secretary may consider such data and evidence to constitute substantial evidence for purposes of the preceding sentence.''.

(b) WOMEN AND MINORITIES.—Section 505(b)(1) (21 U.S.C. 355(b)(1)) is amended by adding at the end the following: ''The Secretary shall, in consultation with the Director of the National Institutes of Health and with representatives of the drug manufacturing industry, review and develop guidance, as appropriate, on the inclusion of women and minorities in clinical trials required by clause (A).''.

SEC. 116. MANUFACTURING CHANGES FOR DRUGS.

(a) IN GENERAL.—Chapter V, as amended by section 112, is amended by inserting after section 506 the following section:

''SEC. 506A. MANUFACTURING CHANGES.

''(a) IN GENERAL.—With respect to a drug for which there is in effect an approved application under section 505 or 512 or a license under section 351 of the Public Health Service Act, a change from the manufacturing process approved pursuant to such application or license may be made, and the drug as made with the change may be distributed, if—

''(1) the holder of the approved application or license (referred to in this section as a 'holder') has validated the effects of the change in accordance with subsection (b); and

''(2)(A) in the case of a major manufacturing change, the holder has complied with the requirements of subsection (c); or

''(B) in the case of a change that is not a major manufacturing change, the holder complies with the applicable requirements of subsection (d).

''(b) VALIDATION OF EFFECTS OF CHANGES.—For purposes of subsection (a)(1), a drug made with a manufacturing change (whether a major manufacturing change or otherwise) may be distributed only if, before distribution of the drug as so made, the holder involved validates the effects of the change on the identity, strength, quality, purity, and potency of the drug as the identity, strength, quality, purity, and potency may relate to the safety or effectiveness of the drug.

''(c) MAJOR MANUFACTURING CHANGES.—

''(1) REQUIREMENT OF SUPPLEMENTAL APPLICATION.—For purposes of subsection (a)(2)(A), a drug made with a major manufacturing change may be distributed only if, before the distribution of the drug as so made, the holder involved submits to the Secretary a supplemental application for such change and the Secretary approves the application. The application shall contain such information as the Secretary determines to be appropriate, and shall include the information developed under subsection (b) by the holder in validating the effects of the change.

''(2) CHANGES QUALIFYING AS MAJOR CHANGES.—For purposes of subsection (a)(2)(A), a major manufacturing change is a manufacturing change that is determined by the Secretary to have substantial potential to adversely affect the identity, strength, quality, purity, or potency of the drug as they may relate to the safety or effectiveness of a drug. Such a change includes a change that—

''(A) is made in the qualitative or quantitative formulation of the drug involved or

in the specifications in the approved application or license referred to in subsection (a) for the drug (unless exempted by the Secretary by regulation or guidance from the requirements of this subsection);

''(B) is determined by the Secretary by regulation or guidance to require completion of an appropriate clinical study demonstrating equivalence of the drug to the drug as manufactured without the change; or

''(C) is another type of change determined by the Secretary by regulation or guidance to have a substantial potential to adversely affect the safety or effectiveness of the drug.

''(d) OTHER MANUFACTURING CHANGES.—

''(1) IN GENERAL.—For purposes of subsection (a)(2)(B), the Secretary may regulate drugs made with manufacturing changes that are not major manufacturing changes as follows:

''(A) The Secretary may in accordance with paragraph (2) authorize holders to distribute such drugs without submitting a supplemental application for such changes.

''(B) The Secretary may in accordance with paragraph (3) require that, prior to the distribution of such drugs, holders submit to the Secretary supplemental applications for such changes.

''(C) The Secretary may establish categories of such changes and designate categories to which subparagraph (A) applies and categories to which subparagraph (B) applies.

''(2) CHANGES NOT REQUIRING SUPPLEMENTAL APPLICATION.—

''(A) SUBMISSION OF REPORT.—A holder making a manufacturing change to which paragraph (1)(A) applies shall submit to the Secretary a report on the change, which shall contain such information as the Secretary determines to be appropriate, and which shall include the information developed under subsection (b) by the holder in validating the effects of the change. The report shall be submitted by such date as the Secretary may specify.

''(B) AUTHORITY REGARDING ANNUAL REPORTS.—In the case of a holder that during a single year makes more than one manufacturing change to which paragraph (1)(A) applies, the Secretary may in carrying out subparagraph (A) authorize the holder to comply with such subparagraph by submitting a single report for the year that provides the information required in such subparagraph for all the changes made by the holder during the year.

''(3) CHANGES REQUIRING SUPPLEMENTAL APPLICATION.—

''(A) SUBMISSION OF SUPPLEMENTAL APPLICATION.—The supplemental application required under paragraph (1)(B) for a manufacturing change shall contain such information as the Secretary determines to be appropriate, which shall include the information developed under subsection (b) by the holder in validating the effects of the change.

''(B) AUTHORITY FOR DISTRIBUTION.—In the case of a manufacturing change to which paragraph (1)(B) applies:

''(i) The holder involved may commence distribution of the drug involved 30 days after the Secretary receives the supplemental application under such paragraph, unless the Secretary notifies the holder within such 30-day period that prior approval of the application is required before distribution may be commenced.

''(ii) The Secretary may designate a category of such changes for the purpose of providing that, in the case of a change that is in such category, the holder involved may commence distribution of the drug involved upon the receipt by the Secretary of a supplemental application for the change.

''(iii) If the Secretary disapproves the supplemental application, the Secretary may order the manufacturer to cease the distribution of the drugs that have been made with the manufacturing change.''.

(b) TRANSITION RULE.—The amendment made by subsection (a) takes effect upon the effective date of regulations promulgated by the Secretary of Health and Human Services to implement such amendment, or upon the expiration of the 24-month period beginning on the date of the enactment of this Act, whichever occurs first.

SEC. 117. STREAMLINING CLINICAL RESEARCH ON DRUGS.

Section 505(i) (21 U.S.C. 355(i)) is amended—

(1) by redesignating paragraphs (1) through (3) as subparagraphs (A) through (C), respectively;

(2) by inserting ''(1)'' after ''(i)'';

(3) by striking the last two sentences; and

(4) by inserting after paragraph (1) (as designated by paragraph (2) of this section) the following new paragraphs:

''(2) Subject to paragraph (3), a clinical investigation of a new drug may begin 30 days after the Secretary has received from the manufacturer or sponsor of the investigation a submission containing such information about the drug and the clinical investigation, including—

''(A) information on design of the investigation and adequate reports of basic information, certified by the applicant to be accurate reports, necessary to assess the safety of the drug for use in clinical investigation; and

''(B) adequate information on the chemistry and manufacturing of the drug, controls available for the drug, and primary data tabulations from animal or human studies.

''(3)(A) At any time, the Secretary may prohibit the sponsor of an investigation from conducting the investigation (referred to in this paragraph as a 'clinical hold') if the Secretary makes a determination described in subparagraph (B). The Secretary shall specify the basis for the clinical hold, including the specific information available to the Secretary which served as the basis for such clinical hold, and confirm such determination in writing.

''(B) For purposes of subparagraph (A), a determination described in this subparagraph with respect to a clinical hold is that—

''(i) the drug involved represents an unreasonable risk to the safety of the persons who are the subjects of the clinical investigation, taking into account the qualifications of the clinical investigators, information about the drug, the design of the clinical investigation, the condition for which the drug is to be investigated, and the health status of the subjects involved; or

''(ii) the clinical hold should be issued for such other reasons as the Secretary may by regulation establish (including reasons established by regulation before the date of the enactment of the Food and Drug Administration Modernization Act of 1997).

''(C) Any written request to the Secretary from the sponsor of an investigation that a clinical hold be removed shall receive a decision, in writing and specifying the reasons therefor, within 30 days after receipt of such request. Any such request shall include sufficient information to support the removal of such clinical hold.

''(4) Regulations under paragraph (1) shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where it is not feasible or it is contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Secretary reports on the investigational use of drugs.''.

SEC. 118. DATA REQUIREMENTS FOR DRUGS AND BIOLOGICS.

Within 12 months after the date of enactment of this Act, the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall issue guidance that describes when abbreviated study reports may be submitted, in lieu of full reports, with a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)) and with a biologics license application under section 351 of the Public Health Service Act (42 U.S.C. 262) for certain types of studies. Such guidance shall describe the kinds of studies for which abbreviated reports are appropriate and the appropriate abbreviated report formats.

SEC. 119. CONTENT AND REVIEW OF APPLICATIONS.

(a) SECTION 505(b).—Section 505(b) (21 U.S.C. 355(b)) is amended by adding at the end the following:

''(4)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1) or under section 351 of the Public Health Service Act, which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

''(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection or section 351 of the Public Health Service Act if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of the clinical trials. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant upon request.

''(C) Any agreement regarding the parameters of the design and size of clinical trials of a new drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

''(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

''(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance division personnel unless such field or compliance division personnel demonstrate to the reviewing division why such decision should be modified.

''(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

''(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection or section 351 of the Public Health Service Act (including all scientific and medical matters, chemistry, manufacturing, and controls).''.

(b) SECTION 505(j).—

(1) AMENDMENT.—Section 505(j) (21 U.S.C 355(j)) is amended—

(A) by redesignating paragraphs (3) through (8) as paragraphs (4) through (9), respectively; and

(B) by adding after paragraph (2) the following:

''(3)(A) The Secretary shall issue guidance for the individuals who review applications submitted under paragraph (1), which shall relate to promptness in conducting the review, technical excellence, lack of bias and conflict of interest, and knowledge of regulatory and scientific standards, and which shall apply equally to all individuals who review such applications.

''(B) The Secretary shall meet with a sponsor of an investigation or an applicant for approval for a drug under this subsection if the sponsor or applicant makes a reasonable written request for a meeting for the purpose of reaching agreement on the design and size of bioavailability and bioequivalence studies needed for approval of such application. The sponsor or applicant shall provide information necessary for discussion and agreement on the design and size of such studies. Minutes of any such meeting shall be prepared by the Secretary and made available to the sponsor or applicant.

''(C) Any agreement regarding the parameters of design and size of bioavailability and bioequivalence studies of a drug under this paragraph that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Such agreement shall not be changed after the testing begins, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (D) by the director of the reviewing division, that a substantial scientific issue essential to determining the safety or effectiveness of the drug has been identified after the testing has begun.

''(D) A decision under subparagraph (C)(ii) by the director shall be in writing and the Secretary shall provide to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant will be present and at which the director will document the scientific issue involved.

''(E) The written decisions of the reviewing division shall be binding upon, and may not directly or indirectly be changed by, the field or compliance office personnel unless such field or compliance office personnel demonstrate to the reviewing division why such decision should be modified.

''(F) No action by the reviewing division may be delayed because of the unavailability of information from or action by field personnel unless the reviewing division determines that a delay is necessary to assure the marketing of a safe and effective drug.

''(G) For purposes of this paragraph, the reviewing division is the division responsible for the review of an application for approval of a drug under this subsection (including scientific matters, chemistry, manufacturing, and controls).''.

(2) CONFORMING AMENDMENTS.—Section 505(j) (21 U.S.C. 355(j)), as amended by paragraph (1), is further amended—

(A) in paragraph (2)(A)(i), by striking ''(6)'' and inserting ''(7)'';

(B) in paragraph (4) (as redesignated in paragraph (1)), by striking ''(4)'' and inserting ''(5)'';

(C) in paragraph (4)(I) (as redesignated in paragraph (1)), by striking ''(5)'' and inserting ''(6)''; and

(D) in paragraph (7)(C) (as redesignated in paragraph (1)), by striking ''(5)'' each place it occurs and inserting ''(6)''.

SEC. 120. SCIENTIFIC ADVISORY PANELS.

Section 505 (21 U.S.C. 355) is amended by adding at the end the following:

''(n)(1) For the purpose of providing expert scientific advice and recommendations to the Secretary regarding a clinical investigation of a drug or the approval for marketing of a drug under section 505 or section 351 of the Public Health Service Act, the Secretary shall establish panels of experts or use panels of experts established before the date of enactment of the Food and Drug Administration Modernization Act of 1997, or both.

''(2) The Secretary may delegate the appointment and oversight authority granted under section 904 to a director of a center or successor entity within the Food and Drug Administration.

''(3) The Secretary shall make appointments to each panel established under paragraph (1) so that each panel shall consist of—

''(A) members who are qualified by training and experience to evaluate the safety and effectiveness of the drugs to be referred to the panel and who, to the extent feasible, possess skill and experience in the development, manufacture, or utilization of such drugs;

''(B) members with diverse expertise in such fields as clinical and administrative medicine, pharmacy, pharmacology, pharmacoeconomics, biological and physical sciences, and other related professions;

''(C) a representative of consumer interests, and a representative of interests of the drug manufacturing industry not directly affected by the matter to be brought before the panel; and

''(D) two or more members who are specialists or have other expertise in the particular disease or condition for which the drug under review is proposed to be indicated.

Scientific, trade, and consumer organizations shall be afforded an opportunity to nominate individuals for appointment to the panels. No individual who is in the regular full-time employ of the United States and engaged in the administration of this Act may be a voting member of any panel. The Secretary shall designate one of the members of each panel to serve as chairman thereof.

''(4) Each member of a panel shall publicly disclose all conflicts of interest that member may have with the work to be undertaken by the panel. No member of a panel may vote on any matter where the member or the immediate family of such member could gain financially from the advice given to the Secretary. The Secretary may grant a waiver of any conflict of interest requirement upon public disclosure of such conflict of interest if such waiver is necessary to afford the panel essential expertise, except that the Secretary may not grant a waiver for a member of a panel when the member's own scientific work is involved.

''(5) The Secretary shall, as appropriate, provide education and training to each new panel member before such member participates in a panel's activities, including education regarding requirements under this Act and related regulations of the Secretary, and the administrative processes and procedures related to panel meetings.

''(6) Panel members (other than officers or employees of the United States), while attending meetings or conferences of a panel or otherwise engaged in its business, shall be entitled to receive compensation for each day so engaged, including traveltime, at rates to be fixed by the Secretary, but not to exceed the daily equivalent of the rate in effect for positions classified above grade GS–15 of the General Schedule. While serving away from their homes or regular places of business, panel members may be allowed travel expenses (including per diem in lieu of subsistence) as authorized by section 5703 of title 5, United States Code, for persons in the Government service employed intermittently.

''(7) The Secretary shall ensure that scientific advisory panels meet regularly and at appropriate intervals so that any matter to be reviewed by such a panel can be presented to the panel not more than 60 days after the matter is ready for such review. Meetings of the panel may be held using electronic communication to convene the meetings.

''(8) Within 90 days after a scientific advisory panel makes recommendations on any matter under its review, the Food and Drug Administration official responsible for the matter shall review the conclusions and recommendations of the panel, and notify the affected persons of the final decision on the matter, or of the reasons that no such decision has been reached. Each such final decision shall be documented including the rationale for the decision.''.

SEC. 121. POSITRON EMISSION TOMOGRAPHY.

(a) REGULATION OF COMPOUNDED POSITRON EMISSION TOMOGRAPHY DRUGS.—Section 201 (21 U.S.C. 321) is amended by adding at the end the following:

''(ii) The term 'compounded positron emission tomography drug'—

''(1) means a drug that—

''(A) exhibits spontaneous disintegration of unstable nuclei by the emission of positrons and is used for the purpose of providing dual photon positron emission tomographic diagnostic images; and

''(B) has been compounded by or on the order of a practitioner who is licensed by a State to compound or order compounding for a drug described in subparagraph (A), and is compounded in accordance with that State's law, for a patient or for research, teaching, or quality control; and

''(2) includes any nonradioactive reagent, reagent kit, ingredient, nuclide generator, accelerator, target material, electronic synthesizer, or other apparatus or computer program to be used in the preparation of such a drug.''.

(b) ADULTERATION.—

(1) IN GENERAL.—Section 501(a) (21 U.S.C. 351(a)) is amended by striking ''; or (3)'' and inserting the following: ''; or (C) if it is a compounded positron emission tomography drug and the methods used in, or the facilities and controls used for, its compounding, processing, packing, or holding do not conform to or are not operated or administered in conformity with the positron emission tomography compounding standards and the official monographs of the United States Pharmacopoeia to assure that such drug meets the requirements of this Act as to safety and has the identity and strength, and meets the quality and purity characteristics, that it purports or is represented to possess; or (3)''.

(2) SUNSET.—Section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) shall not apply 4 years after the date of enactment of this Act or 2 years after the date on which the Secretary of Health and Human Services establishes the requirements described in subsection (c)(1)(B), whichever is later.

(c) REQUIREMENTS FOR REVIEW OF APPROVAL PROCEDURES AND CURRENT GOOD MANUFACTURING PRACTICES FOR POSITRON EMISSION TOMOGRAPHY.—

(1) PROCEDURES AND REQUIREMENTS.—

(A) IN GENERAL.—In order to take account of the special characteristics of positron emission tomography drugs and the special techniques and processes required to produce these drugs, not later than 2 years after the date of enactment of this Act, the Secretary of Health and Human Services shall establish—

(i) appropriate procedures for the approval of positron emission tomography drugs pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355); and

(ii) appropriate current good manufacturing practice requirements for such drugs.

(B) CONSIDERATIONS AND CONSULTATION.—In establishing the procedures and requirements required by subparagraph (A), the Secretary of Health and Human Services shall take due account of any relevant differences between not-for-profit institutions that compound the drugs for their patients and commercial manufacturers of the drugs. Prior to establishing the procedures and requirements, the Secretary of Health and Human Services shall consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists licensed to make or use positron emission tomography drugs.

(2) SUBMISSION OF NEW DRUG APPLICATIONS AND ABBREVIATED NEW DRUG APPLICATIONS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the Secretary of Health and Human Services shall not require the submission of new drug applications or abbreviated new drug applications under subsection (b) or (j) of section 505 (21 U.S.C. 355), for compounded positron emission tomography drugs that are not adulterated drugs described in section 501(a)(2)(C) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)(2)(C)) (as amended by subsection (b)), for a period of 4 years after the date of enactment of this Act, or for 2 years after the date on which the Secretary establishes procedures and requirements under paragraph (1), whichever is longer.

(B) EXCEPTION.—Nothing in this Act shall prohibit the voluntary submission of such applications or the review of such applications by the Secretary of Health and Human Services. Nothing in this Act shall constitute an exemption for a positron emission tomography drug from the requirements of regulations issued under section 505(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(i)).

(d) REVOCATION OF CERTAIN INCONSISTENT DOCUMENTS.—Within 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register a notice terminating the application of the following notices and rule:

(1) A notice entitled ''Regulation of Positron Emission Tomography Radiopharmaceutical Drug Products; Guidance; Public Workshop'', published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10594.

(2) A notice entitled ''Draft Guideline on the Manufacture of Positron Emission Tomography Radiopharmaceutical Drug Products; Availability'', published in the Federal Register on February 27, 1995, 60 Fed. Reg. 10593.

(3) A final rule entitled ''Current Good Manufacturing Practice for Finished Pharmaceuticals; Positron Emission Tomography'', published in the Federal Register on April 22, 1997, 62 Fed. Reg. 19493 (codified at part 211 of title 21, Code of Federal Regulations).

(e) DEFINITION.—As used in this section, the term ''compounded positron emission tomography drug'' has the meaning given the term in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321).

SEC. 122. REQUIREMENTS FOR RADIOPHARMACEUTICALS.

(a) REQUIREMENTS.—

(1) REGULATIONS.—

(A) PROPOSED REGULATIONS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services, after consultation with patient advocacy groups, associations, physicians licensed to use radiopharmaceuticals, and the regulated industry, shall issue proposed regulations governing the approval of radiopharmaceuticals. The regulations shall provide that the determination of the safety and effectiveness of such a radiopharmaceutical under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (42 U.S.C. 262) shall include consideration of the proposed use of the radiopharmaceutical in the practice of medicine, the pharmacological and toxicological activity of the radiopharmaceutical (including any carrier or ligand component of the radiopharmaceutical), and the estimated absorbed radiation dose of the radiopharmaceutical.

(B) FINAL REGULATIONS.—Not later than 18 months after the date of enactment of this Act, the Secretary shall promulgate final regulations governing the approval of the radiopharmaceuticals.

(2) SPECIAL RULE.—In the case of a radiopharmaceutical, the indications for which such radiopharmaceutical is approved for marketing may, in appropriate cases, refer to manifestations of disease (such as biochemical, physiological, anatomic, or pathological processes) common to, or present in, one or more disease states.

(b) DEFINITION.—In this section, the term ''radiopharmaceutical'' means—

(1) an article—

(A) that is intended for use in the diagnosis or monitoring of a disease or a manifestation of a disease in humans; and

(B) that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons; or

(2) any nonradioactive reagent kit or nuclide generator that is intended to be used in the preparation of any such article.

SEC. 123. MODERNIZATION OF REGULATION.

(a) LICENSES.—

(1) IN GENERAL.—Section 351(a) of the Public Health Service (42 U.S.C. 262(a)) is amended to read as follows:

''(a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

''(A) a biologics license is in effect for the biological product; and

''(B) each package of the biological product is plainly marked with—

''(i) the proper name of the biological product contained in the package;

''(ii) the name, address, and applicable license number of the manufacturer of the biological product; and

''(iii) the expiration date of the biological product.

''(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.

''(B) The Secretary shall approve a biologics license application—

''(i) on the basis of a demonstration that—

''(I) the biological product that is the subject of the application is safe, pure, and potent; and

''(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

''(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).''.

(2) ELIMINATION OF EXISTING LICENSE REQUIREMENT.—Section 351(d) of the Public Health Service Act (42 U.S.C. 262(d)) is amended—

(A) by striking ''(d)(1)'' and all that follows through ''of this section.'';

(B) in paragraph (2)—

(i) by striking ''(2)(A) Upon'' and inserting ''(d)(1) Upon'' and

(ii) by redesignating subparagraph (B) as paragraph (2); and

(C) in paragraph (2) (as so redesignated by subparagraph (B)(ii))—

(i) by striking ''subparagraph (A)'' and inserting ''paragraph (1)''; and

(ii) by striking ''this subparagraph'' each place it appears and inserting ''this paragraph''.

(b) LABELING.—Section 351(b) of the Public Health Service Act (42 U.S.C. 262(b)) is amended to read as follows:

''(b) No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.''.

(c) INSPECTION.—Section 351(c) of the Public Health Service Act (42 U.S.C. 262(c)) is amended by striking ''virus, serum,'' and all that follows and inserting ''biological product.''.

(d) DEFINITION; APPLICATION.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

''(i) In this section, the term 'biological product' means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.''.

(e) CONFORMING AMENDMENT.—Section 503(g)(4) (21 U.S.C. 353(g)(4)) is amended—

(1) in subparagraph (A)—

(A) by striking ''section 351(a)'' and inserting ''section 351(i)''; and

(B) by striking ''262(a)'' and inserting ''262(i)''; and

(2) in subparagraph (B)(iii), by striking ''product or establishment license under subsection (a) or (d)'' and inserting ''biologics license application under subsection (a)''.

(f) SPECIAL RULE.—The Secretary of Health and Human Services shall take measures to minimize differences in the review and approval of products required to have approved biologics license applications under section 351 of the Public Health Service Act (42 U.S.C. 262) and products required to have approved new drug applications under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(1)).

(g) APPLICATION OF FEDERAL FOOD, DRUG, AND COSMETIC ACT.—Section 351 of the Public Health Service Act (42 U.S.C. 262), as amended by subsection (d), is further amended by adding at the end the following:

''(j) The Federal Food, Drug, and Cosmetic Act applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.''.

(h) EXAMINATIONS AND PROCEDURES.—Paragraph (3) of section 353(d) of the Public

Health Service Act (42 U.S.C. 263a(d)) is amended to read as follows:

''(3) EXAMINATIONS AND PROCEDURES.—The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

''(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

''(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.''.

SEC. 124. PILOT AND SMALL SCALE MANUFACTURE.

(a) HUMAN DRUGS.—Section 505(c) (21 U.S.C. 355(c)) is amended by adding at the end the following:

''(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

(b) ANIMAL DRUGS.—Section 512(c) (21 U.S.C. 360b(c)) is amended by adding at the end the following:

''(4) A drug manufactured in a pilot or other small facility may be used to demonstrate the safety and effectiveness of the drug and to obtain approval for the drug prior to manufacture of the drug in a larger facility, unless the Secretary makes a determination that a full scale production facility is necessary to ensure the safety or effectiveness of the drug.''.

SEC. 125. INSULIN AND ANTIBIOTICS.

(a) CERTIFICATION OF DRUGS CONTAINING INSULIN.—

(1) AMENDMENT.—Section 506 (21 U.S.C. 356), as in effect before the date of the enactment of this Act, is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 301(j) (21 U.S.C. 331(j)) is amended by striking ''506, 507,''.

(B) Subsection (k) of section 502 (21 U.S.C. 352) is repealed.

(C) Sections 301(i)(1), 510(j)(1)(A), and 510(j)(1)(D) (21 U.S.C. 331(i)(1), 360(j)(1)(A), 360(j)(1)(D)) are each amended by striking '', 506, 507,''.

(D) Section 801(d)(1) (21 U.S.C. 381(d)(1)) is amended by inserting after ''503(b)'' the following: ''or composed wholly or partly of insulin''.

(E) Section 8126(h)(2) of title 38, United States Code, is amended by inserting ''or'' at the end of subparagraph (B), by striking ''; or'' at the end of subparagraph (C) and inserting a period, and by striking subparagraph (D).

(b) CERTIFICATION OF ANTIBIOTICS.—

(1) AMENDMENT.—Section 507 (21 U.S.C. 357) is repealed.

(2) CONFORMING AMENDMENTS.—

(A) Section 201(aa) (21 U.S.C. 321(aa)) is amended by striking out ''or 507'', section 201(dd) (21 U.S.C. 321(dd)) is amended by striking ''507,'', and section 201(ff)(3)(A) (21 U.S.C. 321(ff)(3)(A)) is amended by striking '', certified as an antibiotic under section 507,''.

(B) Section 301(e) (21 U.S.C. 331(e)) is amended by striking ''507(d) or (g),''.

(C) Section 306(d)(4)(B)(ii) (21 U.S.C. 335a(d)(4)(B)(ii)) is amended by striking ''or 507''.

(D) Section 502 (21 U.S.C. 352) is amended by striking subsection (l).

(E) Section 520(l) (21 U.S.C. 360j(l)) is amended by striking paragraph (4) and by striking ''or Antibiotic Drugs'' in the subsection heading.

(F) Section 525(a) (21 U.S.C. 360aa(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), and by redesignating paragraph (3) as paragraph (2).

(G) Section 525(a) (21 U.S.C. 360aa(a)) is amended by striking '', certification of such drug for such disease or condition under section 507,''.

(H) Section 526(a)(1) (21 U.S.C. 360bb) is amended by striking ''the submission of an application for certification of the drug under section 507,'', by inserting ''or'' at the end of subparagraph (A), by striking subparagraph (B), and by redesignating subparagraph (C) as subparagraph (B).

(I) Section 526(b) (21 U.S.C. 360bb(b)) is amended—

(i) in paragraph (1), by striking '', a certificate was issued for the drug under section 507,''; and

(ii) in paragraph (2) by striking '', a certificate has not been issued for the drug under section 507,'' and by striking '', approval of an application for certification under section 507,''.

(J) Section 527(a) (21 U.S.C. 360cc(a)) is amended by inserting ''or'' at the end of paragraph (1), by striking paragraph (2), by redesignating paragraph (3) as paragraph (2), and by striking '', issue another certification under section 507,''.

(K) Section 527(b) (21 U.S.C. 360cc(b)) is amended by striking '', if a certification is issued under section 507 for such a drug,'', '', of the issuance of the certification under section 507,'', '', issue another certification under section 507,'', '', of such certification,'', '', of the certification,'', and '', issuance of other certications,''.

(L) Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking '', section 507 (d) or (g),''.

(M) Section 735(1) (21 U.S.C. 379g(1)(C)) is amended by inserting ''or'' at the end of subparagraph (B), by striking subparagraph (C), and by redesignating subparagraph (D) as subparagraph (C).

(N) Subparagraphs (A)(ii) and (B) of sections 5(b)(1) of the Orphan Drug Act (21 U.S.C. 360ee(b)(1)(A), 360ee(b)(1)(B)) are each amended by striking ''or 507''.

(O) Section 45C(b)(2)(A)(ii)(II) of the Internal Revenue Code of 1986 is amended by striking ''or 507''.

(P) Section 156(f)(4)(B) of title 35, United States Code, is amended by striking ''507,'' each place it occurs.

(c) EXPORTATION.—Section 802 (21 U.S.C. 382) is amended by adding at the end the following:

''(i) Insulin and antibiotic drugs may be exported without regard to the requirements in this section if the insulin and antibiotic drugs meet the requirements of section 801(e)(1).''.

(d) TRANSITION.—

(1) IN GENERAL.—An application that was approved by the Secretary of Health and Human Services before the date of the enactment of this Act for the marketing of an antibiotic drug under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357), as in effect on the day before the date of the enactment of this Act, shall, on and after such date of enactment, be considered to be an application that was submitted and filed under section 505(b) of such Act (21 U.S.C. 355(b)) and approved for safety and effectiveness under section 505(c) of such Act (21 U.S.C. 355(c)), except that if such application for marketing was in the form of an abbreviated application, the application shall be considered to have been filed and approved under section 505(j) of such Act (21 U.S.C. 355(j)).

(2) EXCEPTION.—The following subsections of section 505 (21 U.S.C 355) shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of such Act (21 U.S.C. 357) before the date of the enactment of this Act:

(A)(i) Subsections (c)(2), (d)(6), (e)(4), (j)(2)(A)(vii), (j)(2)(A)(viii), (j)(2)(B), (j)(4)(B), and (j)(4)(D); and

(ii) The third and fourth sentences of subsection (b)(1) (regarding the filing and publication of patent information); and

(B) Subsections (b)(2)(A), (b)(2)(B), (b)(3), and (c)(3) if the investigations relied upon by the applicant for approval of the application were not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted.

(3) PUBLICATION.—For purposes of this section, the Secretary is authorized to make available to the public the established name of each antibiotic drug that was the subject of any application for marketing received by the Secretary for Health and Human Services under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 357) before the date of enactment of this Act.

(e) DEFINITION.—Section 201 (21 U.S.C. 321), as amended by section 121(a)(1), is further amended by adding at the end the following:

''(jj) The term 'antibiotic drug' means any drug (except drugs for use in animals other than humans) composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other drug intended for human use containing any quantity of any chemical substance which is produced by a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution (including a chemically synthesized equivalent of any such substance) or any derivative thereof.''.

SEC. 126. ELIMINATION OF CERTAIN LABELING REQUIREMENTS.

(a) PRESCRIPTION DRUGS.—Section 503(b)(4) (21 U.S.C. 353(b)(4)) is amended to read as follows:

''(4)(A) A drug that is subject to paragraph (1) shall be deemed to be misbranded if at any time prior to dispensing the label of the drug fails to bear, at a minimum, the symbol 'Rx only'.

''(B) A drug to which paragraph (1) does not apply shall be deemed to be misbranded if at any time prior to dispensing the label of the drug bears the symbol described in subparagraph (A).''.

(b) MISBRANDED DRUG.—Section 502(d) (21 U.S.C. 352(d)) is repealed.

(c) CONFORMING AMENDMENTS.—

(1) Section 503(b)(1) (21 U.S.C. 353(b)(1)) is amended—

(A) by striking subparagraph (A); and

(B) by redesignating subparagraphs (B) and (C) as subparagraphs (A) and (B), respectively.

(2) Section 503(b)(3) (21 U.S.C. 353(b)(3)) is amended by striking ''section 502(d) and''.

(3) Section 102(9)(A) of the Controlled Substances Act (21 U.S.C. 802(9)(A)) is amended—

(A) in clause (i), by striking ''(i)''; and

(B) by striking ''(ii)'' and all that follows.

SEC. 127. APPLICATION OF FEDERAL LAW TO PRACTICE OF PHARMACY COMPOUNDING.

(a) AMENDMENT.—Chapter V is amended by inserting after section 503 (21 U.S.C. 353) the following:

''SEC. 503A. PHARMACY COMPOUNDING.

''(a) IN GENERAL.—Sections 501(a)(2)(B), 502(f)(1), and 505 shall not apply to a drug

product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

''(1) is by—

''(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

''(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

''(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

''(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

''(i) the licensed pharmacist or licensed physician; and

''(ii)(I) such individual patient for whom the prescription order will be provided; or

''(II) the physician or other licensed practitioner who will write such prescription order.

''(b) COMPOUNDED DRUG.—

''(1) LICENSED PHARMACIST AND LICENSED PHYSICIAN.—A drug product may be compounded under subsection (a) if the licensed pharmacist or licensed physician—

''(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

''(i) that—

''(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

''(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

''(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d);

''(ii) that are manufactured by an establishment that is registered under section 510 (including a foreign establishment that is registered under section 510(i)); and

''(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

''(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

''(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

''(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

''(2) DEFINITION.—For purposes of paragraph (1)(D), the term 'essentially a copy of a commercially available drug product' does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

''(3) DRUG PRODUCT.—A drug product may be compounded under subsection (a) only if—

''(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

''(B) such drug product is compounded in a State—

''(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

''(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

''(c) ADVERTISING AND PROMOTION.—A drug may be compounded under subsection (a) only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

''(d) REGULATIONS.—

''(1) IN GENERAL.—The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A), the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

''(2) LIMITING COMPOUNDING.—The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

''(e) APPLICATION.—This section shall not apply to—

''(1) compounded positron emission tomography drugs as defined in section 201(ii); or

''(2) radiopharmaceuticals.

''(f) DEFINITION.—As used in this section, the term 'compounding' does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.''.

(b) EFFECTIVE DATE.—Section 503A of the Federal Food, Drug, and Cosmetic Act, added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act.

SEC. 128. REAUTHORIZATION OF CLINICAL PHARMACOLOGY PROGRAM.

Section 2 of Public Law 102–222 (105 Stat. 1677) is amended—

(1) in subsection (a), by striking ''a grant'' and all that follows through ''Such grant'' and inserting the following: ''grants for a pilot program for the training of individuals in clinical pharmacology at appropriate medical schools. Such grants''; and

(2) in subsection (b), by striking ''to carry out this section'' and inserting '', and for fiscal years 1998 through 2002 $3,000,000 for each fiscal year, to carry out this section''.

SEC. 129. REGULATIONS FOR SUNSCREEN PRODUCTS.

Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall issue regulations for over-the-counter sunscreen products for the prevention or treatment of sunburn.

SEC. 130. REPORTS OF POSTMARKETING APPROVAL STUDIES.

(a) IN GENERAL.—Chapter V, as amended by section 116, is further amended by inserting after section 506A the following:

''SEC. 506B. REPORTS OF POSTMARKETING STUDIES.

''(a) SUBMISSION.—

''(1) IN GENERAL.—A sponsor of a drug that has entered into an agreement with the Secretary to conduct a postmarketing study of a drug shall submit to the Secretary, within 1 year after the approval of such drug and annually thereafter until the study is completed or terminated, a report of the progress of the study or the reasons for the failure of the sponsor to conduct the study. The report shall be submitted in such form as is prescribed by the Secretary in regulations issued by the Secretary.

''(2) AGREEMENTS PRIOR TO EFFECTIVE DATE.—Any agreement entered into between the Secretary and a sponsor of a drug, prior to the date of enactment of the Food and Drug Administration Modernization Act of 1997, to conduct a postmarketing study of a drug shall be subject to the requirements of paragraph (1). An initial report for such an agreement shall be submitted within 6 months after the date of the issuance of the regulations under paragraph (1).

''(b) CONSIDERATION OF INFORMATION AS PUBLIC INFORMATION.—Any information pertaining to a report described in subsection (a) shall be considered to be public information to the extent that the information is necessary—

''(1) to identify the sponsor; and

''(2) to establish the status of a study described in subsection (a) and the reasons, if any, for any failure to carry out the study.

''(c) STATUS OF STUDIES AND REPORTS.—The Secretary shall annually develop and publish in the Federal Register a report that provides information on the status of the postmarketing studies—

''(1) that sponsors have entered into agreements to conduct; and

''(2) for which reports have been submitted under subsection (a)(1).''.

(b) REPORT TO CONGRESSIONAL COMMITTEES.—Not later than October 1, 2001, the Secretary shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Com-

merce of the House of Representatives a report containing—

(1) a summary of the reports submitted under section 506B of the Federal Food, Drug, and Cosmetic Act;

(2) an evaluation of—

(A) the performance of the sponsors referred to in such section in fulfilling the agreements with respect to the conduct of postmarketing studies described in such section of such Act; and

(B) the timeliness of the Secretary's review of the postmarketing studies; and

(3) any legislative recommendations respecting the postmarketing studies.

SEC. 131. NOTIFICATION OF DISCONTINUANCE OF A LIFE SAVING PRODUCT.

(a) IN GENERAL.—Chapter V, as amended by section 130, is further amended by inserting after section 506B the following:

"SEC. 506C. DISCONTINUANCE OF A LIFE SAVING PRODUCT.

''(a) IN GENERAL.—A manufacturer that is the sole manufacturer of a drug—

''(1) that is—

''(A) life-supporting;

''(B) life-sustaining; or

''(C) intended for use in the prevention of a debilitating disease or condition;

''(2) for which an application has been approved under section 505(b) or 505(j); and

''(3) that is not a product that was originally derived from human tissue and was replaced by a recombinant product,

shall notify the Secretary of a discontinuance of the manufacture of the drug at least 6 months prior to the date of the discontinuance.

''(b) REDUCTION IN NOTIFICATION PERIOD.—The notification period required under subsection (a) for a manufacturer may be reduced if the manufacturer certifies to the Secretary that good cause exists for the reduction, such as a situation in which—

''(1) a public health problem may result from continuation of the manufacturing for the 6-month period;

''(2) a biomaterials shortage prevents the continuation of the manufacturing for the 6-month period;

''(3) a liability problem may exist for the manufacturer if the manufacturing is continued for the 6-month period;

''(4) continuation of the manufacturing for the 6-month period may cause substantial economic hardship for the manufacturer;

''(5) the manufacturer has filed for bankruptcy under chapter 7 or 11 of title 11, United States Code; or

''(6) the manufacturer can continue the distribution of the drug involved for 6 months.

''(c) DISTRIBUTION.—To the maximum extent practicable, the Secretary shall distribute information on the discontinuation of the drugs described in subsection (a) to appropriate physician and patient organizations.''.

TITLE II—IMPROVING REGULATION OF DEVICES

SEC. 201. INVESTIGATIONAL DEVICE EXEMPTIONS.

(a) IN GENERAL.—Section 520(g) (21 U.S.C. 360j(g)) is amended by adding at the end the following:

''(6)(A) Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall by regulation establish, with respect to a device for which an exemption under this subsection is in effect, procedures and conditions that, without requiring an additional approval of an application for an exemption or the approval of a supplement to such an application, permit—

''(i) developmental changes in the device (including manufacturing changes) that do not constitute a significant change in design or in basic principles of operation and that are made in response to information gathered during the course of an investigation; and

''(ii) changes or modifications to clinical protocols that do not affect—

''(I) the validity of data or information resulting from the completion of an approved protocol, or the relationship of likely patient risk to benefit relied upon to approve a protocol;

''(II) the scientific soundness of an investigational plan submitted under paragraph (3)(A); or

''(III) the rights, safety, or welfare of the human subjects involved in the investigation.

''(B) Regulations under subparagraph (A) shall provide that a change or modification described in such subparagraph may be made if—

''(i) the sponsor of the investigation determines, on the basis of credible information (as defined by the Secretary) that the applicable conditions under subparagraph (A) are met; and

''(ii) the sponsor submits to the Secretary, not later than 5 days after making the change or modification, a notice of the change or modification.

''(7)(A) In the case of a person intending to investigate the safety or effectiveness of a class III device or any implantable device, the Secretary shall ensure that the person has an opportunity, prior to submitting an application to the Secretary or to an institutional review committee, to submit to the Secretary, for review, an investigational plan (including a clinical protocol). If the applicant submits a written request for a meeting with the Secretary regarding such review, the Secretary shall, not later than 30 days after receiving the request, meet with the applicant for the purpose of reaching agreement regarding the investigational plan (including a clinical protocol). The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan (including a clinical protocol) for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device.

''(B) Any agreement regarding the parameters of an investigational plan (including a clinical protocol) that is reached between the Secretary and a sponsor or applicant shall be reduced to writing and made part of the administrative record by the Secretary. Any such agreement shall not be changed, except—

''(i) with the written agreement of the sponsor or applicant; or

''(ii) pursuant to a decision, made in accordance with subparagraph (C) by the director of the office in which the device involved is reviewed, that a substantial scientific issue essential to determining the safety or effectiveness of the device involved has been identified.

''(C) A decision under subparagraph (B)(ii) by the director shall be in writing, and may be made only after the Secretary has provided to the sponsor or applicant an opportunity for a meeting at which the director and the sponsor or applicant are present and at which the director documents the scientific issue involved.''.

(b) ACTION ON APPLICATION.—Section 515(d)(1)(B) (21 U.S.C. 360e(d)(1)(B)) is amended by adding at the end the following:

''(iii) The Secretary shall accept and review statistically valid and reliable data and any other information from investigations conducted under the authority of regulations required by section 520(g) to make a determination of whether there is a reasonable assurance of safety and effectiveness of a device subject to a pending application under this section if—

''(I) the data or information is derived from investigations of an earlier version of the device, the device has been modified during or after the investigations (but prior to submission of an application under subsection (c)) and such a modification of the device does not constitute a significant change in the design or in the basic principles of operation of the device that would invalidate the data or information; or

''(II) the data or information relates to a device approved under this section, is available for use under this Act, and is relevant to the design and intended use of the device for which the application is pending.''.

SEC. 202. SPECIAL REVIEW FOR CERTAIN DEVICES.

Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) by redesignating paragraph (3) as paragraph (4); and

(2) by adding at the end the following:

''(5) In order to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions, the Secretary shall provide review priority for devices—

''(A) representing breakthrough technologies,

''(B) for which no approved alternatives exist,

''(C) which offer significant advantages over existing approved alternatives, or

''(D) the availability of which is in the best interest of the patients.''.

SEC. 203. EXPANDING HUMANITARIAN USE OF DEVICES.

Section 520(m) (21 U.S.C. 360j(m)) is amended—

(1) in paragraph (2), by adding after and below subparagraph (C) the following sentences:

''The request shall be in the form of an application submitted to the Secretary. Not later than 75 days after the date of the receipt of the application, the Secretary shall issue an order approving or denying the application.'';

(2) in paragraph (4)—

(A) in subparagraph (B), by inserting after ''(2)(A)'' the following: '', unless a physician determines in an emergency situation that approval from a local institutional review committee can not be obtained in time to prevent serious harm or death to a patient''; and

(B) by adding after and below subparagraph (B) the following:

''In a case described in subparagraph (B) in which a physician uses a device without an approval from an institutional review committee, the physician shall, after the use of the device, notify the chairperson of the local institutional review committee of such use. Such notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.'';

(3) by amending paragraph (5) to read as follows:

''(5) The Secretary may require a person granted an exemption under paragraph (2) to demonstrate continued compliance with the requirements of this subsection if the Secretary believes such demonstration to be necessary to protect the public health or if the Secretary has reason to believe that the criteria for the exemption are no longer met.''; and

(4) by amending paragraph (6) to read as follows:

''(6) The Secretary may suspend or withdraw an exemption from the effectiveness requirements of sections 514 and 515 for a humanitarian device only after providing notice and an opportunity for an informal hearing.''.

SEC. 204. DEVICE STANDARDS.

(a) ALTERNATIVE PROCEDURE.—Section 514 (21 U.S.C. 360d) is amended by adding at the end the following:

''Recognition of a Standard

''(c)(1)(A) In addition to establishing a performance standard under this section, the Secretary shall, by publication in the Federal Register, recognize all or part of an appropriate standard established by a nationally or internationally recognized standard development organization for which a person may submit a declaration of conformity in order to meet a premarket submission requirement or other requirement under this Act to which such standard is applicable.

''(B) If a person elects to use a standard recognized by the Secretary under subparagraph (A) to meet the requirements described in such subparagraph, the person shall provide a declaration of conformity to the Secretary that certifies that the device is in conformity with such standard. A person may elect to use data, or information, other than data required by a standard recognized under subparagraph (A) to meet any requirement regarding devices under this Act.

''(2) The Secretary may withdraw such recognition of a standard through publication of a notice in the Federal Register if the Secretary determines that the standard is no longer appropriate for meeting a requirement regarding devices under this Act.

''(3)(A) Subject to subparagraph (B), the Secretary shall accept a declaration of conformity that a device is in conformity with a standard recognized under paragraph (1) unless the Secretary finds—

''(i) that the data or information submitted to support such declaration does not demonstrate that the device is in conformity with the standard identified in the declaration of conformity; or

''(ii) that the standard identified in the declaration of conformity is not applicable to the particular device under review.

''(B) The Secretary may request, at any time, the data or information relied on by the person to make a declaration of conformity with respect to a standard recognized under paragraph (1).

''(C) A person making a declaration of conformity with respect to a standard recognized under paragraph (1) shall maintain the data and information demonstrating conformity of the device to the standard for a period of two years after the date of the classification or approval of the device by the Secretary or a period equal to the expected design life of the device, whichever is longer.''.

(b) SECTION 301.—Section 301 (21 U.S.C. 331) is amended by adding at the end the following:

''(x) The falsification of a declaration of conformity submitted under section 514(c) or the failure or refusal to provide data or information requested by the Secretary under paragraph (3) of such section.''.

(c) SECTION 501.—Section 501(e) (21 U.S.C. 351(e)) is amended—

(1) by striking ''(e)'' and inserting ''(e)(1)''; and

(2) by inserting at the end the following:

''(2) If it is declared to be, purports to be, or is represented as, a device that is in conformity with any standard recognized under section 514(c) unless such device is in all respects in conformity with such standard.''.

(d) CONFORMING AMENDMENTS.—Section 514(a) (21 U.S.C. 360d(a)) is amended—

(1) in paragraph (1), in the second sentence, by striking ''under this section'' and inserting ''under subsection (b)'';

(2) in paragraph (2), in the matter preceding subparagraph (A), by striking ''under this section'' and inserting ''under subsection (b)'';

(3) in paragraph (3), by striking ''under this section'' and inserting ''under subsection (b)''; and

(4) in paragraph (4), in the matter preceding subparagraph (A), by striking ''this section'' and inserting ''this subsection and subsection (b)''.

SEC. 205. SCOPE OF REVIEW; COLLABORATIVE DETERMINATIONS OF DEVICE DATA REQUIREMENTS.

(a) SECTION 513(a).—Section 513(a)(3) (21 U.S.C. 360c(a)(3)) is amended by adding at the end the following:

''(C) In making a determination of a reasonable assurance of the effectiveness of a device for which an application under section 515 has been submitted, the Secretary shall consider whether the extent of data that otherwise would be required for approval of the application with respect to effectiveness can be reduced through reliance on postmarket controls.

''(D)(i) The Secretary, upon the written request of any person intending to submit an application under section 515, shall meet with such person to determine the type of valid scientific evidence (within the meaning of subparagraphs (A) and (B)) that will be necessary to demonstrate for purposes of approval of an application the effectiveness of a device for the conditions of use proposed by such person. The written request shall include a detailed description of the device, a detailed description of the proposed conditions of use of the device, a proposed plan for determining whether there is a reasonable assurance of effectiveness, and, if available, information regarding the expected performance from the device. Within 30 days after such meeting, the Secretary shall specify in writing the type of valid scientific evidence that will provide a reasonable assurance that a device is effective under the conditions of use proposed by such person.

''(ii) Any clinical data, including one or more well-controlled investigations, specified in writing by the Secretary for demonstrating a reasonable assurance of device effectiveness shall be specified as result of a determination by the Secretary that such data are necessary to establish device effectiveness. The Secretary shall consider, in consultation with the applicant, the least burdensome appropriate means of evaluating device effectiveness that would have a reasonable likelihood of resulting in approval.

''(iii) The determination of the Secretary with respect to the specification of valid scientific evidence under clauses (i) and (ii) shall be binding upon the Secretary, unless such determination by the Secretary could be contrary to the public health.''.

(b) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)(1)) is amended by adding at the end the following:

''(C) To facilitate reviews of reports submitted to the Secretary under section 510(k), the Secretary shall consider the extent to which reliance on postmarket controls may expedite the classification of devices under subsection (f)(1) of this section.

''(D) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.

''(E)(i) Any determination by the Secretary of the intended use of a device shall be based upon the proposed labeling submitted in a report for the device under section 510(k). However, when determining that a device can be found substantially equivalent to a legally marketed device, the director of the organizational unit responsible for regulating devices (in this subparagraph referred to as the 'Director') may require a statement in labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if, after providing an opportunity for consultation with the person who submitted such report, the Director determines and states in writing—

''(I) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and

''(II) that such use could cause harm.

''(ii) Such determination shall—

''(I) be provided to the person who submitted the report within 10 days from the date of the notification of the Director's concerns regarding the proposed labeling;

''(II) specify the limitations on the use of the device not included in the proposed labeling; and

''(III) find the device substantially equivalent if the requirements of subparagraph (A) are met and if the labeling for such device conforms to the limitations specified in subclause (II).

''(iii) The responsibilities of the Director under this subparagraph may not be delegated.

''(iv) This subparagraph has no legal effect after the expiration of the five-year period beginning on the date of the enactment of the Food and Drug Administration Modernization Act of 1997.''.

(c) SECTION 515(d).—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by adding after and below clause (ii) the following:

''In making the determination whether to approve or deny the application, the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.''; and

(2) by adding after paragraph (5) (as added by section 202(2)) the following:

''(6)(A)(i) A supplemental application shall be required for any change to a device subject to an approved application under this subsection that affects safety or effectiveness, unless such change is a modification in a manufacturing procedure or method of manufacturing and the holder of the approved application submits a written notice to the Secretary that describes in detail the change, summarizes the data or information supporting the change, and informs the Secretary that the change has been made under the requirements of section 520(f).

''(ii) The holder of an approved application who submits a notice under clause (i) with respect to a manufacturing change of a device may distribute the device 30 days after the date on which the Secretary receives the notice, unless the Secretary within such 30-day period notifies the holder that the notice is not adequate and describes such further information or action that is required for acceptance of such change. If the Secretary notifies the holder that a supplemental application is required, the Secretary shall review the supplement within 135 days after the receipt of the supplement. The time used by the Secretary to review the notice of the manufacturing change shall be deducted from the 135-day review period if the notice meets appropriate content requirements for premarket approval supplements.

''(B)(i) Subject to clause (ii), in reviewing a supplement to an approved application, for an incremental change to the design of a de-

vice that affects safety or effectiveness, the Secretary shall approve such supplement if—

''(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

''(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

''(ii) The Secretary may require, when necessary, additional clinical data to evaluate the design modification of the device to provide a reasonable assurance of safety and effectiveness.''.

SEC. 206. PREMARKET NOTIFICATION.

(a) SECTION 510.—Section 510 (21 U.S.C. 360) is amended—

(1) in subsection (k), in the matter preceding paragraph (1), by adding after ''report to the Secretary'' the following: ''or person who is accredited under section 523(a)''; and

(2) by adding at the end the following subsections:

''(l) A report under subsection (k) is not required for a device intended for human use that is exempted from the requirements of this subsection under subsection (m) or is within a type that has been classified into class I under section 513. The exception established in the preceding sentence does not apply to any class I device that is intended for a use which is of substantial importance in preventing impairment of human health, or to any class I device that presents a potential unreasonable risk of illness or injury.

''(m)(1) Not later than 60 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall publish in the Federal Register a list of each type of class II device that does not require a report under subsection (k) to provide reasonable assurance of safety and effectiveness. Each type of class II device identified by the Secretary as not requiring the report shall be exempt from the requirement to provide a report under subsection (k) as of the date of the publication of the list in the Federal Register.

''(2) Beginning on the date that is 1 day after the date of the publication of a list under this subsection, the Secretary may exempt a class II device from the requirement to submit a report under subsection (k), upon the Secretary's own initiative or a petition of an interested person, if the Secretary determines that such report is not necessary to assure the safety and effectiveness of the device. The Secretary shall publish in the Federal Register notice of the intent of the Secretary to exempt the device, or of the petition, and provide a 30-day period for public comment. Within 120 days after the issuance of the notice in the Federal Register, the Secretary shall publish an order in the Federal Register that sets forth the final determination of the Secretary regarding the exemption of the device that was the subject of the notice. If the Secretary fails to respond to a petition within 180 days of receiving it, the petition shall be deemed to be granted.''.

(b) SECTION 513(f).—Section 513(f) (21 U.S.C. 360c(f)) is amended by adding at the end the following:

''(5) The Secretary may not withhold a determination of the initial classification of a device under paragraph (1) because of a failure to comply with any provision of this Act unrelated to a substantial equivalence decision, including a finding that the facility in which the device is manufactured is not in compliance with good manufacturing requirements as set forth in regulations of the Secretary under section 520(f) (other than a finding that there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health).''.

(c) SECTION 513(i).—Section 513(i)(1) (21 U.S.C. 360c(i)), as amended by section 205(b), is amended—

(1) in subparagraph (A)(ii)—

(A) in subclause (I), by striking ''clinical data'' and inserting ''appropriate clinical or scientific data'' and by inserting ''or a person accredited under section 523'' after ''Secretary''; and

(B) in subclause (II), by striking ''efficacy'' and inserting ''effectiveness''; and

(2) by adding at the end the following:

''(F) Not later than 270 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall issue guidance specifying the general principles that the Secretary will consider in determining when a specific intended use of a device is not reasonably included within a general use of such device for purposes of a determination of substantial equivalence under subsection (f) or section 520(l).''.

SEC. 207. EVALUATION OF AUTOMATIC CLASS III DESIGNATION.

Section 513(f) (21 U.S.C. 360c(f)), as amended by section 206(b), is amended—

(1) in paragraph (1)—

(A) in subparagraph (B), by striking ''paragraph (2)'' and inserting ''paragraph (3)''; and

(B) in the last sentence, by striking ''paragraph (2)'' and inserting ''paragraph (2) or (3)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (3) and (4), respectively; and

(3) by inserting after paragraph (1) the following:

''(2)(A) Any person who submits a report under section 510(k) for a type of device that has not been previously classified under this Act, and that is classified into class III under paragraph (1), may request, within 30 days after receiving written notice of such a classification, the Secretary to classify the device under the criteria set forth in subparagraphs (A) through (C) of subsection (a)(1). The person may, in the request, recommend to the Secretary a classification for the device. Any such request shall describe the device and provide detailed information and reasons for the recommended classification.

''(B)(i) Not later than 60 days after the date of the submission of the request under subparagraph (A), the Secretary shall by written order classify the device involved. Such classification shall be the initial classification of the device for purposes of paragraph (1) and any device classified under this paragraph shall be a predicate device for determining substantial equivalence under paragraph (1).

''(ii) A device that remains in class III under this subparagraph shall be deemed to be adulterated within the meaning of section 501(f)(1)(B) until approved under section 515 or exempted from such approval under section 520(g).

''(C) Within 30 days after the issuance of an order classifying a device under this paragraph, the Secretary shall publish a notice in the Federal Register announcing such classification.''.

SEC. 208. CLASSIFICATION PANELS.

Section 513(b) (21 U.S.C. 360c(b)) is amended by adding at the end the following:

''(5) Classification panels covering each type of device shall be scheduled to meet at such times as may be appropriate for the Secretary to meet applicable statutory deadlines.

''(6)(A) Any person whose device is specifically the subject of review by a classification panel shall have—

''(i) the same access to data and information submitted to a classification panel (except for data and information that are not available for public disclosure under section 552 of title 5, United States Code) as the Secretary;

''(ii) the opportunity to submit, for review by a classification panel, information that is based on the data or information provided in the application submitted under section 515 by the person, which information shall be submitted to the Secretary for prompt transmittal to the classification panel; and

''(iii) the same opportunity as the Secretary to participate in meetings of the panel.

''(B) Any meetings of a classification panel shall provide adequate time for initial presentations and for response to any differing views by persons whose devices are specifically the subject of a classification panel review, and shall encourage free and open participation by all interested persons.

''(7) After receiving from a classification panel the conclusions and recommendations of the panel on a matter that the panel has reviewed, the Secretary shall review the conclusions and recommendations, shall make a final decision on the matter in accordance with section 515(d)(2), and shall notify the affected persons of the decision in writing and, if the decision differs from the conclusions and recommendations of the panel, shall include the reasons for the difference.

''(8) A classification panel under this subsection shall not be subject to the annual chartering and annual report requirements of the Federal Advisory Committee Act.''.

SEC. 209. CERTAINTY OF REVIEW TIMEFRAMES; COLLABORATIVE REVIEW PROCESS.

(a) CERTAINTY OF REVIEW TIMEFRAMES.—Section 510 (21 U.S.C. 360), as amended by section 206(a)(2), is amended by adding at the end the following subsection:

''(n) The Secretary shall review the report required in subsection (k) and make a determination under section 513(f)(1) not later than 90 days after receiving the report.''.

(b) COLLABORATIVE REVIEW PROCESS.—Section 515(d) (21 U.S.C. 360e(d)), as amended by section 202(1), is amended by inserting after paragraph (2) the following:

''(3)(A)(i) The Secretary shall, upon the written request of an applicant, meet with the applicant, not later than 100 days after the receipt of an application that has been filed as complete under subsection (c), to discuss the review status of the application.

''(ii) The Secretary shall, in writing and prior to the meeting, provide to the applicant a description of any deficiencies in the application that, at that point, have been identified by the Secretary based on an interim review of the entire application and identify the information that is required to correct those deficiencies.

''(iii) The Secretary shall notify the applicant promptly of—

''(I) any additional deficiency identified in the application, or

''(II) any additional information required to achieve completion of the review and final action on the application,

that was not described as a deficiency in the written description provided by the Secretary under clause (ii).

''(B) The Secretary and the applicant may, by mutual consent, establish a different schedule for a meeting required under this paragraph.

SEC. 210. ACCREDITATION OF PERSONS FOR REVIEW OF PREMARKET NOTIFICATION REPORTS.

(a) IN GENERAL.—Subchapter A of chapter V is amended by adding at the end the following:

''SEC. 523. ACCREDITED PERSONS.

''(a) IN GENERAL.—

''(1) REVIEW AND CLASSIFICATION OF DEVICES.—Not later than 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall, subject to paragraph (3), accredit persons for the purpose of reviewing

reports submitted under section 510(k) and making recommendations to the Secretary regarding the initial classification of devices under section 513(f)(1).

''(2) REQUIREMENTS REGARDING REVIEW.—

''(A) IN GENERAL.—In making a recommendation to the Secretary under paragraph (1), an accredited person shall notify the Secretary in writing of the reasons for the recommendation.

''(B) TIME PERIOD FOR REVIEW.—Not later than 30 days after the date on which the Secretary is notified under subparagraph (A) by an accredited person with respect to a recommendation of an initial classification of a device, the Secretary shall make a determination with respect to the initial classification.

''(C) SPECIAL RULE.—The Secretary may change the initial classification under section 513(f)(1) that is recommended under paragraph (1) by an accredited person, and in such case shall provide to such person, and the person who submitted the report under section 510(k) for the device, a statement explaining in detail the reasons for the change.

''(3) CERTAIN DEVICES.—

''(A) IN GENERAL.—An accredited person may not be used to perform a review of—

''(i) a class III device;

''(ii) a class II device which is intended to be permanently implantable or life sustaining or life supporting; or

''(iii) a class II device which requires clinical data in the report submitted under section 510(k) for the device, except that the number of class II devices to which the Secretary applies this clause for a year, less the number of such reports to which clauses (i) and (ii) apply, may not exceed 6 percent of the number that is equal to the total number of reports submitted to the Secretary under such section for such year less the number of such reports to which such clauses apply for such year.

''(B) ADJUSTMENT.—In determining for a year the ratio described in subparagraph (A)(iii), the Secretary shall not include in the numerator class III devices that the Secretary reclassified into class II, and the Secretary shall include in the denominator class II devices for which reports under section 510(k) were not required to be submitted by reason of the operation of section 510(m).

''(b) ACCREDITATION.—

''(1) PROGRAMS.—The Secretary shall provide for such accreditation through programs administered by the Food and Drug Administration, other government agencies, or by other qualified nongovernment organizations.

''(2) ACCREDITATION.—

''(A) IN GENERAL.—Not later than 180 days after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall establish and publish in the Federal Register criteria to accredit or deny accreditation to persons who request to perform the duties specified in subsection (a). The Secretary shall respond to a request for accreditation within 60 days of the receipt of the request. The accreditation of such person shall specify the particular activities under subsection (a) for which such person is accredited.

''(B) WITHDRAWAL OF ACCREDITATION.—The Secretary may suspend or withdraw accreditation of any person accredited under this paragraph, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to act in a manner that is consistent with the purposes of this section.

''(C) PERFORMANCE AUDITING.—To ensure that persons accredited under this section will continue to meet the standards of accreditation, the Secretary shall—

''(i) make onsite visits on a periodic basis to each accredited person to audit the performance of such person; and

''(ii) take such additional measures as the Secretary determines to be appropriate.

''(D) ANNUAL REPORT.—The Secretary shall include in the annual report required under section 903(g) the names of all accredited persons and the particular activities under subsection (a) for which each such person is accredited and the name of each accredited person whose accreditation has been withdrawn during the year.

''(3) QUALIFICATIONS.—An accredited person shall, at a minimum, meet the following requirements:

''(A) Such person may not be an employee of the Federal Government.

''(B) Such person shall be an independent organization which is not owned or controlled by a manufacturer, supplier, or vendor of devices and which has no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor.

''(C) Such person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation.

''(D) Such person shall not engage in the design, manufacture, promotion, or sale of devices.

''(E) The operations of such person shall be in accordance with generally accepted professional and ethical business practices and shall agree in writing that as a minimum it will—

''(i) certify that reported information accurately reflects data reviewed;

''(ii) limit work to that for which competence and capacity are available;

''(iii) treat information received, records, reports, and recommendations as proprietary information;

''(iv) promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

''(v) protect against the use, in carrying out subsection (a) with respect to a device, of any officer or employee of the person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the person, and the officers and employees of the person, have maintained compliance with requirements under this clause relating to financial conflicts of interest.

''(4) SELECTION OF ACCREDITED PERSONS.—The Secretary shall provide each person who chooses to use an accredited person to receive a section 510(k) report a panel of at least two or more accredited persons from which the regulated person may select one for a specific regulatory function.

''(5) COMPENSATION OF ACCREDITED PERSONS.—Compensation for an accredited person shall be determined by agreement between the accredited person and the person who engages the services of the accredited person, and shall be paid by the person who engages such services.

''(c) DURATION.—The authority provided by this section terminates—

''(1) 5 years after the date on which the Secretary notifies Congress that at least 2 persons accredited under subsection (b) are available to review at least 60 percent of the submissions under section 510(k), or

''(2) 4 years after the date on which the Secretary notifies Congress that the Secretary has made a determination described in paragraph (2)(B) of subsection (a) for at least 35 percent of the devices that are subject to review under paragraph (1) of such subsection,

whichever occurs first.''.

(b) RECORDKEEPING.—Section 704 (21 U.S.C. 374) is amended by adding at the end the following:

''(f)(1) A person accredited under section 523 to review reports made under section 510(k) and make recommendations of initial classifications of devices to the Secretary shall maintain records documenting the training qualifications of the person and the employees of the person, the procedures used by the person for handling confidential information, the compensation arrangements made by the person, and the procedures used by the person to identify and avoid conflicts of interest. Upon the request of an officer or employee designated by the Secretary, the person shall permit the officer or employee, at all reasonable times, to have access to, to copy, and to verify, the records.

''(2) Within 15 days after the receipt of a written request from the Secretary to a person accredited under section 523 for copies of records described in paragraph (1), the person shall produce the copies of the records at the place designated by the Secretary.''.

(c) CONFORMING AMENDMENT.—Section 301 (21 U.S.C. 331), as amended by section 204(b), is amended by adding at the end the following:

''(y) In the case of a drug, device, or food—

''(1) the submission of a report or recommendation by a person accredited under section 523 that is false or misleading in any material respect;

''(2) the disclosure by a person accredited under section 523 of confidential commercial information or any trade secret without the express written consent of the person who submitted such information or secret to such person; or

''(3) the receipt by a person accredited under section 523 of a bribe in any form or the doing of any corrupt act by such person associated with a responsibility delegated to such person under this Act.''.

(d) REPORTS ON PROGRAM OF ACCREDITATION.—

(1) COMPTROLLER GENERAL.—

(A) IMPLEMENTATION OF PROGRAM.—Not later than 5 years after the date of the enactment of this Act, the Comptroller General of the United States shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the extent to which the program of accreditation required by the amendment made by subsection (a) has been implemented.

(B) EVALUATION OF PROGRAM.—Not later than 6 months prior to the date on which, pursuant to subsection (c) of section 523 of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a), the authority provided under subsection (a) of such section will terminate, the Comptroller General shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report describing the use of accredited persons under such section 523, including an evaluation of the extent to which such use assisted the Secretary in carrying out the duties of the Secretary under such Act with respect to devices, and the extent to which such use promoted actions which are contrary to the purposes of such Act.

(2) INCLUSION OF CERTAIN DEVICES WITHIN PROGRAM.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report providing a determination by the Secretary of whether, in the program of accreditation established pursuant to the amendment made by subsection (a), the limitation established in clause (iii) of section 523(a)(3)(A) of the Federal Food, Drug, and Cosmetic Act (relating to class II devices for which clinical data are required in reports under section 510(k)) should be removed.

SEC. 211. DEVICE TRACKING.

Effective 90 days after the date of the enactment of this Act, section 519(e) (21 U.S.C. 360i(e)) is amended to read as follows:

''Device Tracking

''(e)(1) The Secretary may by order require a manufacturer to adopt a method of tracking a class II or class III device—

''(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

''(B) which is—

''(i) intended to be implanted in the human body for more than one year, or

''(ii) a life sustaining or life supporting device used outside a device user facility.

''(2) Any patient receiving a device subject to tracking under paragraph (1) may refuse to release, or refuse permission to release, the patient's name, address, social security number, or other identifying information for the purpose of tracking.''.

SEC. 212. POSTMARKET SURVEILLANCE.

Effective 90 days after the date of the enactment of this Act, section 522 (21 U.S.C. 360l) is amended to read as follows:

''POSTMARKET SURVEILLANCE

''SEC. 522. (a) IN GENERAL.—The Secretary may by order require a manufacturer to conduct postmarket surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be—

''(1) implanted in the human body for more than one year, or

''(2) a life sustaining or life supporting device used outside a device user facility.

''(b) SURVEILLANCE APPROVAL.—Each manufacturer required to conduct a surveillance of a device shall, within 30 days of receiving an order from the Secretary prescribing that the manufacturer is required under this section to conduct such surveillance, submit, for the approval of the Secretary, a plan for the required surveillance. The Secretary, within 60 days of the receipt of such plan, shall determine if the person designated to conduct the surveillance has appropriate qualifications and experience to undertake such surveillance and if the plan will result in the collection of useful data that can reveal unforeseen adverse events or other information necessary to protect the public health. The Secretary, in consultation with the manufacturer, may by order require a prospective surveillance period of up to 36 months. Any determination by the Secretary that a longer period is necessary shall be made by mutual agreement between the Secretary and the manufacturer or, if no agreement can be reached, after the completion of a dispute resolution process as described in section 562.''.

SEC. 213. REPORTS.

(a) REPORTS.—Section 519 (21 U.S.C. 360i) is amended—

(1) in subsection (a)—

(A) in the matter preceding paragraph (1), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer'';

(B) in paragraph (4), by striking ''manufacturer, importer, or distributor'' and inserting ''manufacturer or importer'';

(C) in paragraph (7), by adding ''and'' after the semicolon at the end;

(D) in paragraph (8)—

(i) by striking ''manufacturer, importer, or distributor'' each place such term appears and inserting ''manufacturer or importer''; and

(ii) by striking the semicolon at the end and inserting a period;

(E) by striking paragraph (9); and

(F) by inserting at the end the following sentence: ''The Secretary shall by regulation require distributors to keep records and make such records available to the Secretary upon request. Paragraphs (4) and (8) apply to distributors to the same extent and in the same manner as such paragraphs apply to manufacturers and importers.'';

(2) by striking subsection (d); and

(3) in subsection (f), by striking '', importer, or distributor'' each place it appears and inserting ''or importer''.

(b) REGISTRATION.—Section 510(g) (21 U.S.C. 360(g)) is amended—

(1) by redesignating paragraph (4) as paragraph (5);

(2) by inserting after paragraph (3) the following:

''(4) any distributor who acts as a wholesale distributor of devices, and who does not manufacture, repackage, process, or relabel a device; or''; and

(3) by adding at the end the following flush sentence:

''In this subsection, the term 'wholesale distributor' means any person (other than the manufacturer or the initial importer) who distributes a device from the original place of manufacture to the person who makes the final delivery or sale of the device to the ultimate consumer or user.''.

(c) DEVICE USER FACILITIES.—

(1) IN GENERAL.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) in paragraph (1)(C)—

(i) in the first sentence, by striking ''a semi-annual basis'' and inserting ''an annual basis'';

(ii) in the second sentence, by striking ''and July 1''; and

(iii) by striking the matter after and below clause (iv); and

(B) in paragraph (2)—

(i) in subparagraph (A), by inserting ''or'' after the comma at the end;

(ii) in subparagraph (B), by striking '', or'' at the end and inserting a period; and

(iii) by striking subparagraph (C).

(2) SENTINEL SYSTEM.—Section 519(b) (21 U.S.C. 360i(b)) is amended—

(A) by redesignating paragraph (5) as paragraph (6); and

(B) by inserting after paragraph (4) the following paragraph:

''(5) With respect to device user facilities:

''(A) The Secretary shall by regulation plan and implement a program under which the Secretary limits user reporting under paragraphs (1) through (4) to a subset of user facilities that constitutes a representative profile of user reports for device deaths and serious illnesses or serious injuries.

''(B) During the period of planning the program under subparagraph (A), paragraphs (1) through (4) continue to apply.

''(C) During the period in which the Secretary is providing for a transition to the full implementation of the program, paragraphs (1) through (4) apply except to the extent that the Secretary determines otherwise.

''(D) On and after the date on which the program is fully implemented, paragraphs (1) through (4) do not apply to a user facility unless the facility is included in the subset referred to in subparagraph (A).

''(E) Not later than 2 years after the date of the enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the plan developed by the Secretary under subparagraph (A) and the progress that has been made toward the implementation of the plan.''.

SEC. 214. PRACTICE OF MEDICINE.

Chapter IX is amended by adding at the end the following:

''SEC. 906. PRACTICE OF MEDICINE.

''Nothing in this Act shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship. This section shall not limit any existing authority of the Secretary to establish and enforce restrictions on the sale or distribution, or in the labeling, of a device that are part of a determination of substantial equivalence, established as a condition of approval, or promulgated through regulations. Further, this section shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices.''.

SEC. 215. NONINVASIVE BLOOD GLUCOSE METER.

(a) FINDINGS.—The Congress finds that—

(1) diabetes and its complications are a leading cause of death by disease in America;

(2) diabetes affects approximately 16,000,000 Americans and another 650,000 will be diagnosed in 1997;

(3) the total health care-related costs of diabetes total nearly $100,000,000,000 per year;

(4) diabetes is a disease that is managed and controlled on a daily basis by the patient;

(5) the failure to properly control and manage diabetes results in costly and often fatal complications including but not limited to blindness, coronary artery disease, and kidney failure;

(6) blood testing devices are a critical tool for the control and management of diabetes, and existing blood testing devices require repeated piercing of the skin;

(7) the pain associated with existing blood testing devices creates a disincentive for people with diabetes to test blood glucose levels, particularly children;

(8) a safe and effective noninvasive blood glucose meter would likely improve control and management of diabetes by increasing the number of tests conducted by people with diabetes, particularly children; and

(9) the Food and Drug Administration is responsible for reviewing all applications for new medical devices in the United States.

(b) SENSE OF CONGRESS.—It is the sense of the Congress that the availability of a safe, effective, noninvasive blood glucose meter would greatly enhance the health and well-being of all people with diabetes across America and the world.

SEC. 216. USE OF DATA RELATING TO PREMARKET APPROVAL; PRODUCT DEVELOPMENT PROTOCOL.

(a) USE OF DATA RELATING TO PREMARKET APPROVAL.—

(1) IN GENERAL.—Section 520(h)(4) (21 U.S.C. 360j(h)(4)) is amended to read as follows:

''(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 515(c) (including information from clinical and preclinical tests or studies that demonstrate the safety and effectiveness of a device, but excluding descriptions of methods of manufacture and product composition and other trade secrets) shall be available, 6 years after the application has been approved by the Secretary, for use by the Secretary in—

''(i) approving another device;

''(ii) determining whether a product development protocol has been completed, under section 515 for another device;

''(iii) establishing a performance standard or special control under this Act; or

''(iv) classifying or reclassifying another device under section 513 and subsection (l)(2).

''(B) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the

agency actions described in subparagraph (A).''.

(2) CONFORMING AMENDMENTS.—Section 517(a) (21 U.S.C. 360g(a)) is amended—

(A) in paragraph (8), by adding ''or'' at the end;

(B) in paragraph (9), by striking '', or'' and inserting a comma; and

(C) by striking paragraph (10).

(b) PRODUCT DEVELOPMENT PROTOCOL.—Section 515(f)(2) (21 U.S.C. 360e(f)(2)) is amended by striking ''he shall'' and all that follows and inserting the following: ''the Secretary—

''(A) may, at the initiative of the Secretary, refer the proposed protocol to the appropriate panel under section 513 for its recommendation respecting approval of the protocol; or

''(B) shall so refer such protocol upon the request of the submitter, unless the Secretary finds that the proposed protocol and accompanying data which would be reviewed by such panel substantially duplicate a product development protocol and accompanying data which have previously been reviewed by such a panel.''.

SEC. 217. CLARIFICATION OF THE NUMBER OF REQUIRED CLINICAL INVESTIGATIONS FOR APPROVAL.

Section 513(a)(3)(A) (21 U.S.C. 360c(a)(3)(A)) is amended by striking ''clinical investigations'' and inserting ''1 or more clinical investigations''.

TITLE III—IMPROVING REGULATION OF FOOD

SEC. 301. FLEXIBILITY FOR REGULATIONS REGARDING CLAIMS.

Section 403(r) (21 U.S.C. 343(r)) is amended by adding at the end the following:

''(7) The Secretary may make proposed regulations issued under this paragraph effective upon publication pending consideration of public comment and publication of a final regulation if the Secretary determines that such action is necessary—

''(A) to enable the Secretary to review and act promptly on petitions the Secretary determines provide for information necessary to—

''(i) enable consumers to develop and maintain healthy dietary practices;

''(ii) enable consumers to be informed promptly and effectively of important new knowledge regarding nutritional and health benefits of food; or

''(iii) ensure that scientifically sound nutritional and health information is provided to consumers as soon as possible; or

''(B) to enable the Secretary to act promptly to ban or modify a claim under this paragraph.

Such proposed regulations shall be deemed final agency action for purposes of judicial review.''.

SEC. 302. PETITIONS FOR CLAIMS.

Section 403(r)(4)(A)(i) (21 U.S.C. 343(r)(4)(A)(i)) is amended—

(1) by adding after the second sentence the following: ''If the Secretary does not act within such 100 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner.'';

(2) in the fourth sentence (as amended by paragraph (1)) by inserting immediately before the comma the following: ''or the petition is deemed to be denied''; and

(3) by adding at the end the following: ''If the Secretary does not act within such 90 days, the petition shall be deemed to be denied unless an extension is mutually agreed upon by the Secretary and the petitioner. If the Secretary issues a proposed regulation, the rulemaking shall be completed within 540 days of the date the petition is received by the Secretary. If the Secretary does not issue a regulation within such 540 days, the Secretary shall provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate the reasons action on the regulation did not occur within such 540 days.''.

SEC. 303. HEALTH CLAIMS FOR FOOD PRODUCTS.

Section 403(r)(3) (21 U.S.C. 343(r)(3)) is amended by adding at the end thereof the following:

''(C) Notwithstanding the provisions of clauses (A)(i) and (B), a claim of the type described in subparagraph (1)(B) which is not authorized by the Secretary in a regulation promulgated in accordance with clause (B) shall be authorized and may be made with respect to a food if—

''(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, about the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the relationship between a nutrient and a disease or health-related condition to which the claim refers;

''(iii) the claim and the food for which the claim is made are in compliance with clause (A)(ii) and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(D) A claim submitted under the requirements of clause (C) may be made until—

''(i) such time as the Secretary issues a regulation under the standard in clause (B)(i)—

''(I) prohibiting or modifying the claim and the regulation has become effective, or

''(II) finding that the requirements of clause (C) have not been met, including finding that the petitioner has not submitted all the information required by such clause; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (C) have not been met.''.

SEC. 304. NUTRIENT CONTENT CLAIMS.

Section 403(r)(2) (21 U.S.C. 343(r)(2)) is amended by adding at the end the following:

''(G) A claim of the type described in subparagraph (1)(A) for a nutrient, for which the Secretary has not promulgated a regulation under clause (A)(i), shall be authorized and may be made with respect to a food if—

''(i) a scientific body of the United States Government with official responsibility for public health protection or research directly relating to human nutrition (such as the National Institutes of Health or the Centers for Disease Control and Prevention) or the National Academy of Sciences or any of its subdivisions has published an authoritative statement, which is currently in effect, which identifies the nutrient level to which the claim refers;

''(ii) a person has submitted to the Secretary, at least 120 days (during which the Secretary may notify any person who is making a claim as authorized by clause (C) that such person has not submitted all the information required by such clause) before the first introduction into interstate commerce of the food with a label containing the claim, (I) a notice of the claim, which shall include the exact words used in the claim and shall include a concise description of the basis upon which such person relied for determining that the requirements of subclause (i) have been satisfied, (II) a copy of the statement referred to in subclause (i) upon which such person relied in making the claim, and (III) a balanced representation of the scientific literature relating to the nutrient level to which the claim refers;

''(iii) the claim and the food for which the claim is made are in compliance with clauses (A) and (B), and are otherwise in compliance with paragraph (a) and section 201(n); and

''(iv) the claim is stated in a manner so that the claim is an accurate representation of the authoritative statement referred to in subclause (i) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

For purposes of this clause, a statement shall be regarded as an authoritative statement of a scientific body described in subclause (i) only if the statement is published by the scientific body and shall not include a statement of an employee of the scientific body made in the individual capacity of the employee.

''(H) A claim submitted under the requirements of clause (G) may be made until—

''(i) such time as the Secretary issues a regulation—

''(I) prohibiting or modifying the claim and the regulation has become effective, or

''(II) finding that the requirements of clause (G) have not been met, including finding that the petitioner had not submitted all the information required by such clause; or

''(ii) a district court of the United States in an enforcement proceeding under chapter III has determined that the requirements of clause (G) have not been met.''.

SEC. 305. REFERRAL STATEMENTS.

Section 403(r)(2)(B) (21 U.S.C. 343(r)(2)(B)) is amended to read as follows:

''(B) If a claim described in subparagraph (1)(A) is made with respect to a nutrient in a food and the Secretary makes a determination that the food contains a nutrient at a level that increases to persons in the general population the risk of a disease or health-related condition that is diet related, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: 'See nutrition information for ___ content.' The blank shall identify the nutrient associated with the increased disease or health-related condition risk. In making the determination described in this clause, the Secretary shall take into account the significance of the food in the total daily diet.''.

SEC. 306. DISCLOSURE OF IRRADIATION.

Chapter IV (21 U.S.C. 341 et seq.) is amended by inserting after section 403B the following:

''DISCLOSURE

''SEC. 403C. (a) No provision of section 201(n), 403(a), or 409 shall be construed to require on the label or labeling of a food a separate radiation disclosure statement that is more prominent than the declaration of ingredients required by section 403(i)(2).

''(b) In this section, the term 'radiation disclosure statement' means a written statement that discloses that a food has been intentionally subject to radiation.''.

SEC. 307. IRRADIATION PETITION.

Not later than 60 days following the date of the enactment of this Act, the Secretary of Health and Human Services shall make a final determination on any petition pending with the Food and Drug Administration that would permit the irradiation of red meat under section 409(b)(1) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not make such determination, the Secretary shall, not later than 60 days following the date of the enactment of this Act, provide the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate an explanation of the process followed by the Food and Drug Administration in reviewing the petition referred to in paragraph (1) and the reasons action on the petition was delayed.

SEC. 308. GLASS AND CERAMIC WARE.

(a) IN GENERAL.—The Secretary may not implement any requirement which would ban, as an unapproved food additive, lead and cadmium based enamel in the lip and rim area of glass and ceramic ware before the expiration of one year after the date such requirement is published.

(b) LEAD AND CADMIUM BASED ENAMEL.—Unless the Secretary determines, based on available data, that lead and cadmium based enamel on glass and ceramic ware—

(1) which has less than 60 millimeters of decorating area below the external rim, and

(2) which is not, by design, representation, or custom of usage intended for use by children,

is unsafe, the Secretary shall not take any action before January 1, 2003, to ban lead and cadmium based enamel on such glass and ceramic ware. Any action taken after January 1, 2003, to ban such enamel on such glass and ceramic ware as an unapproved food additive shall be taken by regulation and such regulation shall provide that such products shall not be removed from the market before 1 year after publication of the final regulation.

SEC. 309. FOOD CONTACT SUBSTANCES.

(a) FOOD CONTACT SUBSTANCES.—Section 409(a) (21 U.S.C. 348(a)) is amended—

(1) in paragraph (1)—

(A) by striking ''subsection (i)'' and inserting ''subsection (j)''; and

(B) by striking at the end ''or'';

(2) by striking the period at the end of paragraph (2) and inserting ''; or'';

(3) by inserting after paragraph (2) the following:

''(3) in the case of a food additive as defined in this Act that is a food contact substance, there is—

''(A) in effect, and such substance and the use of such substance are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used; or

''(B) a notification submitted under subsection (h) that is effective.''; and

(4) by striking the matter following paragraph (3) (as added by paragraph (3)) and inserting the following flush sentence:

''While such a regulation relating to a food additive, or such a notification under subsection (h)(1) relating to a food additive that is a food contact substance, is in effect, and has not been revoked pursuant to subsection (i), a food shall not, by reason of bearing or containing such a food additive in accordance with the regulation or notification, be considered adulterated under section 402(a)(1).''.

(b) NOTIFICATION FOR FOOD CONTACT SUBSTANCES.—Section 409 (21 U.S.C. 348), as amended by subsection (a), is further amended—

(1) by redesignating subsections (h) and (i), as subsections (i) and (j), respectively;

(2) by inserting after subsection (g) the following:

''Notification Relating to a Food Contact Substance

''(h)(1) Subject to such regulations as may be promulgated under paragraph (3), a manufacturer or supplier of a food contact substance may, at least 120 days prior to the introduction or delivery for introduction into interstate commerce of the food contact substance, notify the Secretary of the identity and intended use of the food contact substance, and of the determination of the manufacturer or supplier that the intended use of such food contact substance is safe under the standard described in subsection (c)(3)(A). The notification shall contain the information that forms the basis of the determination and all information required to be submitted by regulations promulgated by the Secretary.

''(2)(A) A notification submitted under paragraph (1) shall become effective 120 days after the date of receipt by the Secretary and the food contact substance may be introduced or delivered for introduction into interstate commerce, unless the Secretary makes a determination within the 120-day period that, based on the data and information before the Secretary, such use of the food contact substance has not been shown to be safe under the standard described in subsection (c)(3)(A), and informs the manufacturer or supplier of such determination.

''(B) A decision by the Secretary to object to a notification shall constitute final agency action subject to judicial review.

''(C) In this paragraph, the term 'food contact substance' means the substance that is the subject of a notification submitted under paragraph (1), and does not include a similar or identical substance manufactured or prepared by a person other than the manufacturer identified in the notification.

''(3)(A) The process in this subsection shall be utilized for authorizing the marketing of a food contact substance except where the Secretary determines that submission and review of a petition under subsection (b) is necessary to provide adequate assurance of safety, or where the Secretary and any manufacturer or supplier agree that such manufacturer or supplier may submit a petition under subsection (b).

''(B) The Secretary is authorized to promulgate regulations to identify the circumstances in which a petition shall be filed under subsection (b), and shall consider criteria such as the probable consumption of such food contact substance and potential toxicity of the food contact substance in determining the circumstances in which a petition shall be filed under subsection (b).

''(4) The Secretary shall keep confidential any information provided in a notification under paragraph (1) for 120 days after receipt by the Secretary of the notification. After the expiration of such 120 days, the information shall be available to any interested party except for any matter in the notification that is a trade secret or confidential commercial information.

''(5)(A)(i) Except as provided in clause (ii), the notification program established under this subsection shall not operate in any fiscal year unless—

''(I) an appropriation equal to or exceeding the applicable amount under clause (iv) is made for such fiscal year for carrying out such program in such fiscal year; and

''(II) the Secretary certifies that the amount appropriated for such fiscal year for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

''(ii) The Secretary shall, not later than April 1, 1999, begin accepting and reviewing notifications submitted under the notification program established under this subsection if—

''(I) an appropriation equal to or exceeding the applicable amount under clause (iii) is made for the last six months of fiscal year 1999 for carrying out such program during such period; and

''(II) the Secretary certifies that the amount appropriated for such period for the Center for Food Safety and Applied Nutrition of the Food and Drug Administration (exclusive of the appropriation referred to in subclause (I)) equals or exceeds an amount equivalent to one-half the amount appropriated for the Center for fiscal year 1997, excluding any amount appropriated for new programs.

''(iii) For the last six months of fiscal year 1999, the applicable amount under this clause is $1,500,000, or the amount specified in the budget request of the President for the six-month period involved for carrying out the notification program in fiscal year 1999, whichever is less.

''(iv) For fiscal year 2000 and subsequent fiscal years, the applicable amount under this clause is $3,000,000, or the amount specified in the budget request of the President for the fiscal year involved for carrying out the notification program under this subsection, whichever is less.

''(B) For purposes of carrying out the notification program under this subsection, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 1999 through fiscal year 2003, except that such authorization of appropriations is not effective for a fiscal year for any amount that is less than the applicable amount under clause (iii) or (iv) of subparagraph (A), whichever is applicable.

''(C) Not later than April 1 of fiscal year 1998 and February 1 of each subsequent fiscal year, the Secretary shall submit a report to the Committees on Appropriations of the House of Representatives and the Senate, the Committee on Commerce of the House of Representatives, and the Committee on Labor and Human Resources of the Senate that provides an estimate of the Secretary of the costs of carrying out the notification program established under this subsection for the next fiscal year.

''(6) In this section, the term 'food contact substance' means any substance intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use is not intended to have any technical effect in such food.'';

(3) in subsection (i), as so redesignated by paragraph (1), by adding at the end the following: ''The Secretary shall by regulation prescribe the procedure by which the Secretary may deem a notification under subsection (h) to no longer be effective.''; and

(4) in subsection (j), as so redesignated by paragraph (1), by striking ''subsections (b) to (h)'' and inserting ''subsections (b) to (i)''.

TITLE IV—GENERAL PROVISIONS

SEC. 401. DISSEMINATION OF INFORMATION ON NEW USES.

(a) IN GENERAL.—Chapter V (21 U.S.C. 351 et seq.) is amended by inserting after subchapter C the following:

''SUBCHAPTER D—DISSEMINATION OF TREATMENT INFORMATION

''SEC. 551. REQUIREMENTS FOR DISSEMINATION OF TREATMENT INFORMATION ON DRUGS OR DEVICES.

''(a) IN GENERAL.—Notwithstanding sections 301(d), 502(f), and 505, and section 351 of the Public Health Service Act (42 U.S.C. 262), a manufacturer may disseminate to—

''(1) a health care practitioner;

''(2) a pharmacy benefit manager;

''(3) a health insurance issuer;

''(4) a group health plan; or

''(5) a Federal or State governmental agency;

written information concerning the safety, effectiveness, or benefit of a use not described in the approved labeling of a drug or device if the manufacturer meets the requirements of subsection (b).

''(b) SPECIFIC REQUIREMENTS.—A manufacturer may disseminate information under subsection (a) on a new use only if—

''(1)(A) in the case of drug, there is in effect for the drug an application filed under subsection (b) or (j) of section 505 or a biologics license issued under section 351 of the Public Health Service Act; or

''(B) in the case of a device, the device is being commercially distributed in accordance with a regulation under subsection (d) or (e) of section 513, an order under subsection (f) of such section, or the approval of an application under section 515;

''(2) the information meets the requirements of section 552;

''(3) the information to be disseminated is not derived from clinical research conducted by another manufacturer or if it was derived from research conducted by another manufacturer, the manufacturer disseminating the information has the permission of such other manufacturer to make the dissemination;

''(4) the manufacturer has, 60 days before such dissemination, submitted to the Secretary—

''(A) a copy of the information to be disseminated; and

''(B) any clinical trial information the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience pertinent to the safety of the new use, and a summary of such information;

''(5) the manufacturer has complied with the requirements of section 554 (relating to a supplemental application for such use);

''(6) the manufacturer includes along with the information to be disseminated under this subsection—

''(A) a prominently displayed statement that discloses—

''(i) that the information concerns a use of a drug or device that has not been approved or cleared by the Food and Drug Administration;

''(ii) if applicable, that the information is being disseminated at the expense of the manufacturer;

''(iii) if applicable, the name of any authors of the information who are employees of, consultants to, or have received compensation from, the manufacturer, or who have a significant financial interest in the manufacturer;

''(iv) the official labeling for the drug or device and all updates with respect to the labeling;

''(v) if applicable, a statement that there are products or treatments that have been approved or cleared for the use that is the subject of the information being disseminated pursuant to subsection (a)(1); and

''(vi) the identification of any person that has provided funding for the conduct of a study relating to the new use of a drug or device for which such information is being disseminated; and

''(B) a bibliography of other articles from a scientific reference publication or scientific or medical journal that have been previously published about the use of the drug or device covered by the information disseminated (unless the information already includes such bibliography).

''(c) ADDITIONAL INFORMATION.—If the Secretary determines, after providing notice of such determination and an opportunity for a meeting with respect to such determination, that the information submitted by a manufacturer under subsection (b)(3)(B), with respect to the use of a drug or device for which the manufacturer intends to disseminate information, fails to provide data, analyses, or other written matter that is objective and balanced, the Secretary may require the manufacturer to disseminate—

''(1) additional objective and scientifically sound information that pertains to the safety or effectiveness of the use and is necessary to provide objectivity and balance, including any information that the manufacturer has submitted to the Secretary or, where appropriate, a summary of such information or any other information that the Secretary has authority to make available to the public; and

''(2) an objective statement of the Secretary, based on data or other scientifically sound information available to the Secretary, that bears on the safety or effectiveness of the new use of the drug or device.

''SEC. 552. INFORMATION AUTHORIZED TO BE DISSEMINATED.

''(a) AUTHORIZED INFORMATION.—A manufacturer may disseminate information under section 551 on a new use only if the information—

''(1) is in the form of an unabridged—

''(A) reprint or copy of an article, peer-reviewed by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device involved, which was published in a scientific or medical journal (as defined in section 556(5)), which is about a clinical investigation with respect to the drug or device, and which would be considered to be scientifically sound by such experts; or

''(B) reference publication, described in subsection (b), that includes information about a clinical investigation with respect to the drug or device that would be considered to be scientifically sound by experts qualified by scientific training or experience to evaluate the safety or effectiveness of the drug or device that is the subject of such a clinical investigation; and

''(2) is not false or misleading and would not pose a significant risk to the public health.

''(b) REFERENCE PUBLICATION.—A reference publication referred to in subsection (a)(1)(B) is a publication that—

''(1) has not been written, edited, excerpted, or published specifically for, or at the request of, a manufacturer of a drug or device;

''(2) has not been edited or significantly influenced by a such a manufacturer;

''(3) is not solely distributed through such a manufacturer but is generally available in bookstores or other distribution channels where medical textbooks are sold;

''(4) does not focus on any particular drug or device of a manufacturer that disseminates information under section 551 and does not have a primary focus on new uses of drugs or devices that are marketed or under investigation by a manufacturer supporting the dissemination of information; and

''(5) presents materials that are not false or misleading.

''SEC. 553. ESTABLISHMENT OF LIST OF ARTICLES AND PUBLICATIONS DISSEMINATED AND LIST OF PROVIDERS THAT RECEIVED ARTICLES AND REFERENCE PUBLICATIONS.

''(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if the manufacturer prepares and submits to the Secretary biannually—

''(1) a list containing the titles of the articles and reference publications relating to the new use of drugs or devices that were disseminated by the manufacturer to a person described in section 551(a) for the 6-month period preceding the date on which the manufacturer submits the list to the Secretary; and

''(2) a list that identifies the categories of providers (as described in section 551(a)) that received the articles and reference publications for the 6-month period described in paragraph (1).

''(b) RECORDS.—A manufacturer that disseminates information under section 551 shall keep records that may be used by the manufacturer when, pursuant to section 555, such manufacturer is required to take corrective action and shall be made available to the Secretary, upon request, for purposes of ensuring or taking corrective action pursuant to such section. Such records, at the Secretary's discretion, may identify the recipient of information provided pursuant to section 551 or the categories of such recipients.

''SEC. 554. REQUIREMENT REGARDING SUBMISSION OF SUPPLEMENTAL APPLICATION FOR NEW USE; EXEMPTION FROM REQUIREMENT.

''(a) IN GENERAL.—A manufacturer may disseminate information under section 551 on a new use only if—

''(1)(A) the manufacturer has submitted to the Secretary a supplemental application for such use; or

''(B) the manufacturer meets the condition described in subsection (b) or (c) (relating to a certification that the manufacturer will submit such an application); or

''(2) there is in effect for the manufacturer an exemption under subsection (d) from the requirement of paragraph (1).

''(b) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF COMPLETED STUDIES.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if the manufacturer has submitted to the Secretary an application containing a certification that—

''(1) the studies needed for the submission of a supplemental application for the new use have been completed; and

''(2) the supplemental application will be submitted to the Secretary not later than 6 months after the date of the initial dissemination of information under section 551.

''(c) CERTIFICATION ON SUPPLEMENTAL APPLICATION; CONDITION IN CASE OF PLANNED STUDIES.—

''(1) IN GENERAL.—For purposes of subsection (a)(1)(B), a manufacturer may disseminate information on a new use if—

''(A) the manufacturer has submitted to the Secretary an application containing—

''(i) a proposed protocol and schedule for conducting the studies needed for the submission of a supplemental application for the new use; and

''(ii) a certification that the supplemental application will be submitted to the Secretary not later than 36 months after the date of the initial dissemination of information under section 551 (or, as applicable, not later than such date as the Secretary may specify pursuant to an extension under paragraph (3)); and

''(B) the Secretary has determined that the proposed protocol is adequate and that the schedule for completing such studies is reasonable.

''(2) PROGRESS REPORTS ON STUDIES.—A manufacturer that submits to the Secretary an application under paragraph (1) shall submit to the Secretary periodic reports describing the status of the studies involved.

''(3) EXTENSION OF TIME REGARDING PLANNED STUDIES.—The period of 36 months authorized in paragraph (1)(A)(ii) for the completion of studies may be extended by the Secretary if—

''(A) the Secretary determines that the studies needed to submit such an application cannot be completed and submitted within 36 months; or

''(B) the manufacturer involved submits to the Secretary a written request for the extension and the Secretary determines that the manufacturer has acted with due diligence to conduct the studies in a timely manner, except that an extension under this subparagraph may not be provided for more than 24 additional months.

''(d) EXEMPTION FROM REQUIREMENT OF SUPPLEMENTAL APPLICATION.—

''(1) IN GENERAL.—For purposes of subsection (a)(2), a manufacturer may disseminate information on a new use if—

''(A) the manufacturer has submitted to the Secretary an application for an exemption from meeting the requirement of subsection (a)(1); and

''(B)(i) the Secretary has approved the application in accordance with paragraph (2); or

''(ii) the application is deemed under paragraph (3)(A) to have been approved (unless such approval is terminated pursuant to paragraph (3)(B)).

''(2) CONDITIONS FOR APPROVAL.—The Secretary may approve an application under paragraph (1) for an exemption if the Secretary makes a determination described in subparagraph (A) or (B), as follows:

''(A) The Secretary makes a determination that, for reasons defined by the Secretary, it would be economically prohibitive with respect to such drug or device for the manufacturer to incur the costs necessary for the submission of a supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate)—

''(i) the lack of the availability under law of any period during which the manufacturer would have exclusive marketing rights with respect to the new use involved; and

''(ii) the size of the population expected to benefit from approval of the supplemental application.

''(B) The Secretary makes a determination that, for reasons defined by the Secretary, it would be unethical to conduct the studies necessary for the supplemental application. In making such determination, the Secretary shall consider (in addition to any other considerations the Secretary finds appropriate) whether the new use involved is the standard of medical care for a health condition.

''(3) TIME FOR CONSIDERATION OF APPLICATION; DEEMED APPROVAL.—

''(A) IN GENERAL.—The Secretary shall approve or deny an application under paragraph (1) for an exemption not later than 60 days after the receipt of the application. If the Secretary does not comply with the preceding sentence, the application is deemed to be approved.

''(B) TERMINATION OF DEEMED APPROVAL.—If pursuant to a deemed approval under subparagraph (A) a manufacturer disseminates written information under section 551 on a new use, the Secretary may at any time terminate such approval and under section 555(b)(3) order the manufacturer to cease disseminating the information.

''(e) REQUIREMENTS REGARDING APPLICATIONS.—Applications under this section shall be submitted in the form and manner prescribed by the Secretary.

''SEC. 555. CORRECTIVE ACTIONS; CESSATION OF DISSEMINATION.

''(a) POSTDISSEMINATION DATA REGARDING SAFETY AND EFFECTIVENESS.—

''(1) CORRECTIVE ACTIONS.—With respect to data received by the Secretary after the dissemination of information under section 551 by a manufacturer has begun (whether received pursuant to paragraph (2) or otherwise), if the Secretary determines that the data indicate that the new use involved may not be effective or may present a significant risk to public health, the Secretary shall, after consultation with the manufacturer, take such action regarding the dissemination of the information as the Secretary determines to be appropriate for the protection of the public health, which may include ordering that the manufacturer cease the dissemination of the information.

''(2) RESPONSIBILITIES OF MANUFACTURERS TO SUBMIT DATA.—After a manufacturer disseminates information under section 551, the manufacturer shall submit to the Secretary a notification of any additional knowledge of the manufacturer on clinical research or other data that relate to the safety or effectiveness of the new use involved. If the manufacturer is in possession of the data, the notification shall include the data. The Secretary shall by regulation establish the scope of the responsibilities of manufacturers under this paragraph, including such limits on the responsibilities as the Secretary determines to be appropriate.

''(b) CESSATION OF DISSEMINATION.—

''(1) FAILURE OF MANUFACTURER TO COMPLY WITH REQUIREMENTS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if the Secretary determines that the information being disseminated does not comply with the requirements established in this subchapter. Such an order may be issued only after the Secretary has provided notice to the manufacturer of the intent of the Secretary to issue the order and (unless paragraph (2)(B) applies) has provided an opportunity for a meeting with respect to such intent. If the failure of the manufacturer constitutes a minor violation of this subchapter, the Secretary shall delay issuing the order and provide to the manufacturer an opportunity to correct the violation.

''(2) SUPPLEMENTAL APPLICATIONS.—The Secretary may order a manufacturer to cease the dissemination of information pursuant to section 551 if—

''(A) in the case of a manufacturer that has submitted a supplemental application for a new use pursuant to section 554(a)(1), the Secretary determines that the supplemental application does not contain adequate information for approval of the new use for which the application was submitted;

''(B) in the case of a manufacturer that has submitted a certification under section 554(b), the manufacturer has not, within the 6-month period involved, submitted the supplemental application referred to in the certification; or

''(C) in the case of a manufacturer that has submitted a certification under section 554(c) but has not yet submitted the supplemental application referred to in the certification, the Secretary determines, after an informal hearing, that the manufacturer is not acting with due diligence to complete the studies involved.

''(3) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—If under section 554(d)(3) the Secretary terminates a deemed approval of an exemption, the Secretary may order the manufacturer involved to cease disseminating the information. A manufacturer shall comply with an order under the preceding sentence not later than 60 days after the receipt of the order.

''(c) CORRECTIVE ACTIONS BY MANUFACTURERS.—

''(1) IN GENERAL.—In any case in which under this section the Secretary orders a manufacturer to cease disseminating information, the Secretary may order the manufacturer to take action to correct the information that has been disseminated, except as provided in paragraph (2).

''(2) TERMINATION OF DEEMED APPROVAL OF EXEMPTION REGARDING SUPPLEMENTAL APPLICATIONS.—In the case of an order under subsection (b)(3) to cease disseminating information, the Secretary may not order the manufacturer involved to take action to correct the information that has been disseminated unless the Secretary determines that the new use described in the information would pose a significant risk to the public health.

''SEC. 556. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'health care practitioner' means a physician, or other individual who is a provider of health care, who is licensed under the law of a State to prescribe drugs or devices.

''(2) The terms 'health insurance issuer' and 'group health plan' have the meaning given such terms under section 2791 of the Public Health Service Act.

''(3) The term 'manufacturer' means a person who manufactures a drug or device, or who is licensed by such person to distribute or market the drug or device.

''(4) The term 'new use'—

''(A) with respect to a drug, means a use that is not included in the labeling of the approved drug; and

''(B) with respect to a device, means a use that is not included in the labeling for the approved or cleared device.

''(5) The term 'scientific or medical journal' means a scientific or medical publication—

''(A) that is published by an organization—

''(i) that has an editorial board;

''(ii) that utilizes experts, who have demonstrated expertise in the subject of an article under review by the organization and who are independent of the organization, to review and objectively select, reject, or provide comments about proposed articles; and

''(iii) that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors or contributors involved with the journal or organization;

''(B) whose articles are peer-reviewed and published in accordance with the regular peer-review procedures of the organization;

''(C) that is generally recognized to be of national scope and reputation;

''(D) that is indexed in the Index Medicus of the National Library of Medicine of the National Institutes of Health; and

''(E) that is not in the form of a special supplement that has been funded in whole or in part by one or more manufacturers.

''SEC. 557. RULES OF CONSTRUCTION.

''(a) UNSOLICITED REQUEST.—Nothing in section 551 shall be construed as prohibiting a manufacturer from disseminating information in response to an unsolicited request from a health care practitioner.

''(b) DISSEMINATION OF INFORMATION ON DRUGS OR DEVICES NOT EVIDENCE OF INTENDED USE.—Notwithstanding subsection (a), (f), or (o) of section 502, or any other provision of law, the dissemination of information relating to a new use of a drug or de-

vice, in accordance with section 551, shall not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device. Such dissemination shall not be considered by the Secretary as labeling, adulteration, or misbranding of the drug or device.

''(c) PATENT PROTECTION.—Nothing in section 551 shall affect patent rights in any manner.

''(d) AUTHORIZATION FOR DISSEMINATION OF ARTICLES AND FEES FOR REPRINTS OF ARTICLES.—Nothing in section 551 shall be construed as prohibiting an entity that publishes a scientific journal (as defined in section 556(5)) from requiring authorization from the entity to disseminate an article published by such entity or charging fees for the purchase of reprints of published articles from such entity.''.

(b) PROHIBITED ACT.—Section 301 (21 U.S.C. 331), as amended by section 210, is amended by adding at the end the following:

''(z) The dissemination of information in violation of section 551.''.

(c) REGULATIONS.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall promulgate regulations to implement the amendments made by this section.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of enactment of this Act, or upon the Secretary's issuance of final regulations pursuant to subsection (c), whichever is sooner.

(e) SUNSET.—The amendments made by this section cease to be effective September 30, 2006, or 7 years after the date on which the Secretary promulgates the regulations described in subsection (c), whichever is later.

(f) STUDIES AND REPORTS.—

(1) GENERAL ACCOUNTING OFFICE.—

(A) IN GENERAL.—The Comptroller General of the United States shall conduct a study to determine the impact of subchapter D of chapter V of the Federal Food, Drug, and Cosmetic Act, as added by this section, on the resources of the Department of Health and Human Services.

(B) REPORT.—Not later than January 1, 2002, the Comptroller General of the United States shall prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives a report of the results of the study.

(2) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—

(A) IN GENERAL.—In order to assist Congress in determining whether the provisions of such subchapter should be extended beyond the termination date specified in subsection (e), the Secretary of Health and Human Services shall, in accordance with subparagraph (B), arrange for the conduct of a study of the scientific issues raised as a result of the enactment of such subchapter including issues relating to—

(i) the effectiveness of such subchapter with respect to the provision of useful scientific information to health care practitioners;

(ii) the quality of the information being disseminated pursuant to the provisions of such subchapter;

(iii) the quality and usefulness of the information provided, in accordance with such subchapter, by the Secretary or by the manufacturer at the request of the Secretary; and

(iv) the impact of such subchapter on research in the area of new uses, indications, or dosages, particularly the impact on pediatric indications and rare diseases.

(3) PROCEDURE FOR STUDY.—

(A) IN GENERAL.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct the study required by paragraph (2), and to prepare and submit the report required by subparagraph (B), under an arrangement by which the actual expenses incurred by the Institute of Medicine in conducting the study and preparing the report will be paid by the Secretary. If the Institute of Medicine is unwilling to conduct the study under such an arrangement, the Comptroller General of the United States shall conduct such study.

(B) REPORT.—Not later than September 30, 2005, the Institute of Medicine or the Comptroller General of the United States, as appropriate, shall prepare and submit to the Committee on Labor and Human Resources of the Senate, the Committee on Commerce of the House of Representatives, and the Secretary a report of the results of the study required by paragraph (2). The Secretary, after the receipt of the report, shall make the report available to the public.

SEC. 402. EXPANDED ACCESS TO INVESTIGATIONAL THERAPIES AND DIAGNOSTICS.

Chapter V (21 U.S.C. 351 et seq.), as amended in section 401, is further amended by adding at the end the following:

''SUBCHAPTER E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

"SEC. 561. EXPANDED ACCESS TO UNAPPROVED THERAPIES AND DIAGNOSTICS.

''(a) EMERGENCY SITUATIONS.—The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

''(b) INDIVIDUAL PATIENT ACCESS TO INVESTIGATIONAL PRODUCTS INTENDED FOR SERIOUS DISEASES.—Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

''(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

''(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

''(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

''(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 505(i) or 520(g), including any regulations promulgated under section 505(i) or 520(g), describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

''(c) TREATMENT INVESTIGATIONAL NEW DRUG APPLICATIONS AND TREATMENT INVESTIGATIONAL DEVICE EXEMPTIONS.—Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an 'expanded access protocol'), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

''(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

''(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

''(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 505(i) or investigational device exemption in effect under section 520(g); or

''(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

''(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

''(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 505(i) or 520(g);

''(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

''(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 505(i) or 520(g), including regulations promulgated under section 505(i) or 520(g). The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 402(j)(3) of the Public Health Service Act.

''(d) TERMINATION.—The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

''(e) DEFINITIONS.—In this section, the terms 'investigational drug', 'investigational device', 'treatment investigational new drug application', and 'treatment investigational device exemption' shall have the meanings given the terms in regulations prescribed by the Secretary.''.

SEC. 403. APPROVAL OF SUPPLEMENTAL APPLICATIONS FOR APPROVED PRODUCTS.

(a) STANDARDS.—Not later than 180 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish in the Federal Register standards for the prompt review of supplemental applications submitted for approved articles under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or section 351 of the Public Health Service Act (42 U.S.C. 262).

(b) GUIDANCE TO INDUSTRY.—Not later than 180 days after the date of enactment of this Act, the Secretary shall issue final guidances to clarify the requirements for, and facilitate the submission of data to support, the approval of supplemental applications for the approved articles described in subsection (a). The guidances shall—

(1) clarify circumstances in which published matter may be the basis for approval of a supplemental application;

(2) specify data requirements that will avoid duplication of previously submitted data by recognizing the availability of data previously submitted in support of an original application; and

(3) define supplemental applications that are eligible for priority review.

(c) RESPONSIBILITIES OF CENTERS.—The Secretary shall designate an individual in each center within the Food and Drug Administration (except the Center for Food Safety and Applied Nutrition) to be responsible for—

(1) encouraging the prompt review of supplemental applications for approved articles; and

(2) working with sponsors to facilitate the development and submission of data to support supplemental applications.

(d) COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Food and Drug Administration, the National Institutes of Health, professional medical and scientific societies, and other persons, to identify published and unpublished studies that may support a supplemental application, and to encourage sponsors to make supplemental applications or conduct further research in support of a supplemental application based, in whole or in part, on such studies.

SEC. 404. DISPUTE RESOLUTION.

Subchapter E of chapter V, as added by section 402, is amended by adding at the end the following:

"SEC. 562. DISPUTE RESOLUTION.

''If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act, there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 505(n) or an advisory committee described in section 515(g)(2)(B). Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after the date of the enactment of the Food and Drug Administration Modernization Act of 1997.''.

SEC. 405. INFORMAL AGENCY STATEMENTS.

Section 701 (21 U.S.C. 371) is amended by adding at the end the following:

''(h)(1)(A) The Secretary shall develop guidance documents with public participation and ensure that information identifying the existence of such documents and the documents themselves are made available to the public both in written form and, as feasible, through electronic means. Such documents shall not create or confer any rights for or on any person, although they present the views of the Secretary on matters under the jurisdiction of the Food and Drug Administration.

''(B) Although guidance documents shall not be binding on the Secretary, the Secretary shall ensure that employees of the Food and Drug Administration do not deviate from such guidances without appropriate justification and supervisory concurrence. The Secretary shall provide training to employees in how to develop and use guidance documents and shall monitor the development and issuance of such documents.

''(C) For guidance documents that set forth initial interpretations of a statute or regulation, changes in interpretation or policy that are of more than a minor nature, complex scientific issues, or highly controversial issues, the Secretary shall ensure public participation prior to implementation of guidance documents, unless the Secretary determines that such prior public participation is not feasible or appropriate. In such cases, the Secretary shall provide for public comment upon implementation and take such comment into account.

''(D) For guidance documents that set forth existing practices or minor changes in policy, the Secretary shall provide for public comment upon implementation.

''(2) In developing guidance documents, the Secretary shall ensure uniform nomenclature for such documents and uniform internal procedures for approval of such documents. The Secretary shall ensure that guidance documents and revisions of such documents are properly dated and indicate the nonbinding nature of the documents. The Secretary shall periodically review all guidance documents and, where appropriate, revise such documents.

''(3) The Secretary, acting through the Commissioner, shall maintain electronically and update and publish periodically in the Federal Register a list of guidance documents. All such documents shall be made available to the public.

''(4) The Secretary shall ensure that an effective appeals mechanism is in place to address complaints that the Food and Drug Administration is not developing and using guidance documents in accordance with this subsection.

''(5) Not later than July 1, 2000, the Secretary after evaluating the effectiveness of the Good Guidance Practices document, published in the Federal Register at 62 Fed. Reg. 8961, shall promulgate a regulation consistent with this subsection specifying the policies and procedures of the Food and Drug Administration for the development, issuance, and use of guidance documents.''.

SEC. 406. FOOD AND DRUG ADMINISTRATION MISSION AND ANNUAL REPORT.

(a) MISSION.—Section 903 (21 U.S.C. 393) is amended—

(1) by redesignating subsections (b) and (c) as subsections (d) and (e), respectively; and

(2) by inserting after subsection (a) the following:

''(b) MISSION.—The Administration shall—

''(1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;

''(2) with respect to such products, protect the public health by ensuring that—

''(A) foods are safe, wholesome, sanitary, and properly labeled;

''(B) human and veterinary drugs are safe and effective;

''(C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;

''(D) cosmetics are safe and properly labeled; and

''(E) public health and safety are protected from electronic product radiation;

''(3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and

''(4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.''.

(b) ANNUAL REPORT.—Section 903 (21 U.S.C. 393), as amended by subsection (a), is further amended by adding at the end the following:

''(f) AGENCY PLAN FOR STATUTORY COMPLIANCE.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of the Food and Drug Administration Modernization Act of 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this Act. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.

''(2) OBJECTIVES OF AGENCY PLAN.—The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to—

''(A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this Act;

''(B) maximizing the availability and clarity of information for consumers and patients concerning new products;

''(C) implementing inspection and postmarket monitoring provisions of this Act;

''(D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);

''(E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this Act for the review of all applications and submissions described in subparagraph (A) and submitted after the date of enactment of the Food and Drug Administration Modernization Act of 1997; and

''(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

''(g) ANNUAL REPORT.—The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that—

''(1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f);

''(2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and

''(3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.''.

SEC. 407. INFORMATION SYSTEM.

(a) AMENDMENT.—Chapter VII (21 U.S.C. 371 et seq.) is amended by adding at the end the following:

''SUBCHAPTER D—INFORMATION AND EDUCATION

"SEC. 741. INFORMATION SYSTEM.

''The Secretary shall establish and maintain an information system to track the status and progress of each application or submission (including a petition, notification, or other similar form of request) submitted to the Food and Drug Administration requesting agency action.''.

(b) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services shall submit a report to the Committee on Labor and Human Resources of the Senate and the Committee on Commerce of the House of Representatives on the status of the system to be established under the amendment made by subsection (a), including the projected costs of the system and concerns about confidentiality.

SEC. 408. EDUCATION AND TRAINING.

(a) FOOD AND DRUG ADMINISTRATION.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following section:

"SEC. 742. EDUCATION.

''(a) IN GENERAL.—The Secretary shall conduct training and education programs for the employees of the Food and Drug Administration relating to the regulatory responsibilities and policies established by this Act, including programs for—

''(1) scientific training;

''(2) training to improve the skill of officers and employees authorized to conduct inspections under section 704;

''(3) training to achieve product specialization in such inspections; and

''(4) training in administrative process and procedure and integrity issues.

''(b) INTRAMURAL FELLOWSHIPS AND OTHER TRAINING PROGRAMS.—The Secretary, acting through the Commissioner, may, through fellowships and other training programs, conduct and support intramural research training for predoctoral and postdoctoral scientists and physicians.''.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION.—

(1) IN GENERAL.—Part B of title III of the Public Health Service Act is amended by inserting after section 317F (42 U.S.C. 247b–7) the following:

"SEC. 317G. FELLOWSHIP AND TRAINING PROGRAMS.

''The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish fellowship and training programs to be conducted by such Centers to train individuals to develop skills in epidemiology, surveillance, laboratory analysis, and other disease detection and prevention methods. Such programs shall be designed to enable health professionals and health personnel trained under such programs to work, after receiving such training, in local, State, national, and international efforts toward the prevention and control of diseases, injuries, and disabilities. Such fellowships and training may be administered through the use of either appointment or nonappointment procedures.''.

(2) EFFECTIVE DATE.—The amendment made by this subsection is deemed to have taken effect July 1, 1995.

SEC. 409. CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended by adding at the end of part A the following new section:

"SEC. 905. DEMONSTRATION PROGRAM REGARDING CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.

''(a) IN GENERAL.—The Secretary, acting through the Administrator and in consultation with the Commissioner of Food and Drugs, shall establish a demonstration program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in subsection (b).

''(b) REQUIRED ACTIVITIES.—The activities referred to in subsection (a) are the following:

''(1) The conduct of state-of-the-art clinical and laboratory research for the following purposes:

''(A) To increase awareness of—

''(i) new uses of drugs, biological products, and devices;

''(ii) ways to improve the effective use of drugs, biological products, and devices; and

''(iii) risks of new uses and risks of combinations of drugs and biological products.

''(B) To provide objective clinical information to the following individuals and entities:

''(i) Health care practitioners or other providers of health care goods or services.

''(ii) Pharmacy benefit managers.

''(iii) Health maintenance organizations or other managed health care organizations.

''(iv) Health care insurers or governmental agencies.

''(v) Consumers.

''(C) To improve the quality of health care while reducing the cost of health care through—

''(i) the appropriate use of drugs, biological products, or devices; and

''(ii) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

''(2) The conduct of research on the comparative effectiveness and safety of drugs, biological products, and devices.

''(3) Such other activities as the Secretary determines to be appropriate, except that the grant may not be expended to assist the Secretary in the review of new drugs.

''(c) APPLICATION FOR GRANT.—A grant under subsection (a) may be made only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(d) PEER REVIEW.—A grant under subsection (a) may be made only if the application for the grant has undergone appropriate technical and scientific peer review.

''(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 1998, and $3,000,000 for each of fiscal years 1999 through 2002.''.

SEC. 410. MUTUAL RECOGNITION AGREEMENTS AND GLOBAL HARMONIZATION.

(a) GOOD MANUFACTURING PRACTICE REQUIREMENTS.—Section 520(f)(1)(B) (21 U.S.C. 360j(f)(1)(B)) is amended—

(1) in clause (i), by striking '', and'' at the end and inserting a semicolon;

(2) in clause (ii), by striking the period and inserting ''; and''; and

(3) by inserting after clause (ii) the following:

''(iii) ensure that such regulation conforms, to the extent practicable, with internationally recognized standards defining quality systems, or parts of the standards, for medical devices.''.

(b) HARMONIZATION EFFORTS.—Section 803 (21 U.S.C. 383) is amended by adding at the end the following:

''(c)(1) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in meetings with representatives of other countries to discuss methods and approaches to reduce the burden of regulation and harmonize regulatory requirements if the Secretary determines that such harmonization continues consumer protections consistent with the purposes of this Act.

''(2) The Secretary shall support the Office of the United States Trade Representative, in consultation with the Secretary of Commerce, in efforts to move toward the acceptance of mutual recognition agreements relating to the regulation of drugs, biological products, devices, foods, food additives, and color additives, and the regulation of good manufacturing practices, between the European Union and the United States.

''(3) The Secretary shall regularly participate in meetings with representatives of other foreign governments to discuss and reach agreement on methods and approaches to harmonize regulatory requirements.

''(4) The Secretary shall, not later than 180 days after the date of enactment of the Food and Drug Administration Modernization Act of 1997, make public a plan that establishes a framework for achieving mutual recognition of good manufacturing practices inspections.

''(5) Paragraphs (1) through (4) shall not apply with respect to products defined in section 201(ff).''.

SEC. 411. ENVIRONMENTAL IMPACT REVIEW.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 407, is further amended by adding at the end the following:

''SUBCHAPTER E—ENVIRONMENTAL IMPACT REVIEW

"SEC. 746. ENVIRONMENTAL IMPACT.

''Notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the regulations published in part 25 of title 21, Code of Federal Regulations (as in effect on August 31, 1997) in connection with an action carried out under (or a recommendation or report relating to) this Act, shall be considered to meet the requirements for a detailed statement under section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)).''.

SEC. 412. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND COSMETICS.

(a) NONPRESCRIPTION DRUGS.—Chapter VII (21 U.S.C. 371 et seq.), as amended by section 411, is further amended by adding at the end the following:

''SUBCHAPTER F—NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS AND PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS

"SEC. 751. NATIONAL UNIFORMITY FOR NONPRESCRIPTION DRUGS.

''(a) IN GENERAL.—Except as provided in subsection (b), (c)(1), (d), (e), or (f), no State or political subdivision of a State may establish or continue in effect any requirement—

''(1) that relates to the regulation of a drug that is not subject to the requirements of section 503(b)(1) or 503(f)(1)(A); and

''(2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—

''(1) IN GENERAL.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement that—

''(A) protects an important public interest that would otherwise be unprotected, including the health and safety of children;

''(B) would not cause any drug to be in violation of any applicable requirement or prohibition under Federal law; and

''(C) would not unduly burden interstate commerce.

''(2) TIMELY ACTION.—The Secretary shall make a decision on the exemption of a State or political subdivision requirement under paragraph (1) not later than 120 days after receiving the application of the State or political subdivision under paragraph (1).

''(c) SCOPE.—

''(1) IN GENERAL.—This section shall not apply to—

''(A) any State or political subdivision requirement that relates to the practice of pharmacy; or

''(B) any State or political subdivision requirement that a drug be dispensed only upon the prescription of a practitioner licensed by law to administer such drug.

''(2) SAFETY OR EFFECTIVENESS.—For purposes of subsection (a), a requirement that relates to the regulation of a drug shall be deemed to include any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug.

''(d) EXCEPTIONS.—

''(1) IN GENERAL.—In the case of a drug described in subsection (a)(1) that is not the subject of an application approved under section 505 or section 507 (as in effect on the day before the date of enactment of the Food and Drug Administration Modernization Act of 1997) or a final regulation promulgated by the Secretary establishing conditions under which the drug is generally recognized as safe and effective and not misbranded, subsection (a) shall apply only with respect to a requirement of a State or political subdivision of a State that relates to the same subject as, but is different from or in addition to, or that is otherwise not identical with—

''(A) a regulation in effect with respect to the drug pursuant to a statute described in subsection (a)(2); or

''(B) any other requirement in effect with respect to the drug pursuant to an amendment to such a statute made on or after the date of enactment of the Food and Drug Administration Modernization Act of 1997.

''(2) STATE INITIATIVES.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.

''(e) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(f) STATE ENFORCEMENT AUTHORITY.—Nothing in this section shall prevent a State or political subdivision thereof from enforcing, under any relevant civil or other enforcement authority, a requirement that is identical to a requirement of this Act.''.

(b) INSPECTIONS.—Section 704(a)(1) (21 U.S.C. 374(a)(1)) is amended by striking ''prescription drugs'' each place it appears and inserting ''prescription drugs, nonprescription drugs intended for human use,''.

(c) MISBRANDING.—Subparagraph (1) of section 502(e) (21 U.S.C. 352(e)(1)) is amended to read as follows:

''(1)(A) If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula)—

''(i) the established name (as defined in subparagraph (3)) of the drug, if there is such a name;

''(ii) the established name and quantity or, if determined to be appropriate by the Secretary, the proportion of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not the established name and quantity or if determined to be appropriate by the Secretary, the proportion of any bromides, ether, chloroform, acetanilide, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein, except that the requirement for stating the quantity of the active ingredients, other than the quantity of those specifically named in this subclause, shall not apply to nonprescription drugs not intended for human use; and

''(iii) the established name of each inactive ingredient listed in alphabetical order on the outside container of the retail package and, if determined to be appropriate by the Secretary, on the immediate container, as prescribed in regulation promulgated by the Secretary, except that nothing in this subclause shall be deemed to require that any trade secret be divulged, and except that the requirements of this subclause with respect to alphabetical order shall apply only to nonprescription drugs that are not also cosmetics and that this subclause shall not apply to nonprescription drugs not intended for human use.

''(B) For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) shall be printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient, except that to the extent that compliance with the requirements of subclause (ii) or (iii) of clause (A) or this clause is impracticable, exemptions shall be established by regulations promulgated by the Secretary.''.

(d) COSMETICS.—Subchapter F of chapter VII, as amended by subsection (a), is further amended by adding at the end the following:

''SEC. 752. PREEMPTION FOR LABELING OR PACKAGING OF COSMETICS.

''(a) IN GENERAL.—Except as provided in subsection (b), (d), or (e), no State or political subdivision of a State may establish or continue in effect any requirement for labeling or packaging of a cosmetic that is different from or in addition to, or that is otherwise not identical with, a requirement specifically applicable to a particular cosmetic or class of cosmetics under this Act, the Poison Prevention Packaging Act of 1970 (15 U.S.C. 1471 et seq.), or the Fair Packaging and Labeling Act (15 U.S.C. 1451 et seq.).

''(b) EXEMPTION.—Upon application of a State or political subdivision thereof, the Secretary may by regulation, after notice and opportunity for written and oral presentation of views, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a State or political subdivision requirement for labeling or packaging that—

''(1) protects an important public interest that would otherwise be unprotected;

''(2) would not cause a cosmetic to be in violation of any applicable requirement or prohibition under Federal law; and

''(3) would not unduly burden interstate commerce.

''(c) SCOPE.—For purposes of subsection (a), a reference to a State requirement that relates to the packaging or labeling of a cosmetic means any specific requirement relating to the same aspect of such cosmetic as a requirement specifically applicable to that particular cosmetic or class of cosmetics under this Act for packaging or labeling, including any State requirement relating to public information or any other form of public communication.

''(d) NO EFFECT ON PRODUCT LIABILITY LAW.—Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State.

''(e) STATE INITIATIVE.—This section shall not apply to a State requirement adopted by a State public initiative or referendum enacted prior to September 1, 1997.''.

SEC. 413. FOOD AND DRUG ADMINISTRATION STUDY OF MERCURY COMPOUNDS IN DRUGS AND FOOD.

(a) LIST AND ANALYSIS.—The Secretary of Health and Human Services shall, acting through the Food and Drug Administration—

(1) compile a list of drugs and foods that contain intentionally introduced mercury compounds, and

(2) provide a quantitative and qualitative analysis of the mercury compounds in the list under paragraph (1).

The Secretary shall compile the list required by paragraph (1) within 2 years after the date of enactment of the Food and Drug Administration Modernization Act of 1997 and shall provide the analysis required by paragraph (2) within 2 years after such date of enactment.

(b) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration, shall conduct a study of the effect on humans of the use of mercury compounds in nasal sprays. Such study shall include data from other studies that have been made of such use.

(c) STUDY OF MERCURY SALES.—

(1) STUDY.—The Secretary of Health and Human Services, acting through the Food and Drug Administration and subject to appropriations, shall conduct, or shall contract with the Institute of Medicine of the National Academy of Sciences to conduct, a study of the effect on humans of the use of elemental, organic, or inorganic mercury when offered for sale as a drug or dietary supplement. Such study shall, among other things, evaluate—

(A) the scope of mercury use as a drug or dietary supplement; and

(B) the adverse effects on health of children and other sensitive populations resulting from exposure to, or ingestion or inhalation of, mercury when so used.

In conducting such study, the Secretary shall consult with the Administrator of the Environmental Protection Agency, the Chair of the Consumer Product Safety Commission, and the Administrator of the Agency for Toxic Substances and Disease Registry, and, to the extent the Secretary believes necessary or appropriate, with any other Federal or private entity.

(2) REGULATIONS.—If, in the opinion of the Secretary, the use of elemental, organic, or inorganic mercury offered for sale as a drug or dietary supplement poses a threat to human health, the Secretary shall promulgate regulations restricting the sale of mercury intended for such use. At a minimum, such regulations shall be designed to protect the health of children and other sensitive populations from adverse effects resulting from exposure to, or ingestion or inhalation of, mercury. Such regulations, to the extent feasible, should not unnecessarily interfere with the availability of mercury for use in religious ceremonies.

SEC. 414. INTERAGENCY COLLABORATION.

Section 903 (21 U.S.C. 393), as amended by section 406, is further amended by inserting after subsection (b) the following:

''(c) INTERAGENCY COLLABORATION.—The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.''.

SEC. 415. CONTRACTS FOR EXPERT REVIEW.

Chapter IX (21 U.S.C. 391 et seq.), as amended by section 214, is further amended by adding at the end the following:

"SEC. 907. CONTRACTS FOR EXPERT REVIEW.

''(a) IN GENERAL.—

''(1) AUTHORITY.—The Secretary may enter into a contract with any organization or any individual (who is not an employee of the Department) with relevant expertise, to review and evaluate, for the purpose of making recommendations to the Secretary on, part or all of any application or submission (including a petition, notification, and any other similar form of request) made under this Act for the approval or classification of an article or made under section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)) with respect to a biological product. Any such contract shall be subject to the requirements of section 708 relating to the confidentiality of information.

''(2) INCREASED EFFICIENCY AND EXPERTISE THROUGH CONTRACTS.—The Secretary may use the authority granted in paragraph (1) whenever the Secretary determines that use of a contract described in paragraph (1) will improve the timeliness of the review of an application or submission described in paragraph (1), unless using such authority would reduce the quality, or unduly increase the cost, of such review. The Secretary may use such authority whenever the Secretary determines that use of such a contract will improve the quality of the review of an application or submission described in paragraph (1), unless using such authority would unduly increase the cost of such review. Such improvement in timeliness or quality may include providing the Secretary increased scientific or technical expertise that is necessary to review or evaluate new therapies and technologies.

''(b) REVIEW OF EXPERT REVIEW.—

''(1) IN GENERAL.—Subject to paragraph (2), the official of the Food and Drug Administration responsible for any matter for which expert review is used pursuant to subsection (a) shall review the recommendations of the organization or individual who conducted the expert review and shall make a final decision regarding the matter in a timely manner.

''(2) LIMITATION.—A final decision by the Secretary on any such application or submission shall be made within the applicable prescribed time period for review of the matter as set forth in this Act or in the Public Health Service Act (42 U.S.C. 201 et seq.).''.

SEC. 416. PRODUCT CLASSIFICATION.

Subchapter E of chapter V, as amended by section 404, is further amended by adding at the end the following:

"SEC. 563. CLASSIFICATION OF PRODUCTS.

''(a) REQUEST.—A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this Act for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 503(g) or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

''(b) STATEMENT.—Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

''(c) INACTION OF SECRETARY.—If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.''.

SEC. 417. REGISTRATION OF FOREIGN ESTABLISHMENTS.

Section 510(i) (21 U.S.C. 360(i)) is amended to read as follows:

''(i)(1) Any establishment within any foreign country engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or a device that is imported or offered for import into the United States shall register with the Secretary the name and place of business of the establishment and the name of the United States agent for the establishment.

''(2) The establishment shall also provide the information required by subsection (j).

''(3) The Secretary is authorized to enter into cooperative arrangements with officials of foreign countries to ensure that adequate and effective means are available for purposes of determining, from time to time, whether drugs or devices manufactured, prepared, propagated, compounded, or processed by an establishment described in paragraph (1), if imported or offered for import into the United States, shall be refused admission on any of the grounds set forth in section 801(a).''.

SEC. 418. CLARIFICATION OF SEIZURE AUTHORITY.

Section 304(d)(1) (21 U.S.C. 334(d)(1)) is amended—

(1) in the fifth sentence, by striking ''paragraphs (1) and (2) of section 801(e)'' and inserting ''subparagraphs (A) and (B) of section 801(e)(1)''; and

(2) by inserting after the fifth sentence the following: ''Any person seeking to export an imported article pursuant to any of the provisions of this subsection shall establish that the article was intended for export at the time the article entered commerce.''.

SEC. 419. INTERSTATE COMMERCE.

Section 709 (21 U.S.C. 379a) is amended by striking ''a device'' and inserting ''a device, food, drug, or cosmetic''.

SEC. 420. SAFETY REPORT DISCLAIMERS.

Chapter VII (21 U.S.C. 371 et seq.), as amended by section 412, is further amended by adding at the end the following:

''SUBCHAPTER G—SAFETY REPORTS

"SEC. 756. SAFETY REPORT DISCLAIMERS.

''With respect to any entity that submits or is required to submit a safety report or other information in connection with the safety of a product (including a product that is a food, drug, device, dietary supplement, or cosmetic) under this Act (and any release by the Secretary of that report or information), such report or information shall not be construed to reflect necessarily a conclusion by the entity or the Secretary that the report or information constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or otherwise caused or contributed to a death, serious injury, or serious illness. Such an entity need not admit, and may deny, that the report or information submitted by the entity constitutes an admission that the product involved malfunctioned, caused or contributed to an adverse experience, or caused or contributed to a death, serious injury, or serious illness.''.

SEC. 421. LABELING AND ADVERTISING REGARDING COMPLIANCE WITH STATUTORY REQUIREMENTS.

Section 301 (21 U.S.C. 331) is amended by striking paragraph (l).

SEC. 422. RULE OF CONSTRUCTION.

Nothing in this Act or the amendments made by this Act shall be construed to affect the question of whether the Secretary of Health and Human Services has any authority to regulate any tobacco product, tobacco ingredient, or tobacco additive. Such authority, if any, shall be exercised under the Federal Food, Drug, and Cosmetic Act as in effect on the day before the date of the enactment of this Act.

TITLE V—EFFECTIVE DATE

SEC. 501. EFFECTIVE DATE.

Except as otherwise provided in this Act, this Act and the amendments made by this Act, other than the provisions of and the amendments made by sections 111, 121, 125, and 307, shall take effect 90 days after the date of enactment of this Act.

And the House agree to the same.

That the House recede from its amendment to the title of the bill.

TOM BLILEY,
MICHAEL BILIRAKIS,
JOE BARTON,
JAMES GREENWOOD,
RICHARD BURR,
ED WHITFIELD,
JOHN D. DINGELL,
SHERROD BROWN,
HENRY A. WAXMAN,
RON KLINK,
Managers of the Part of the House.

JIM JEFFORDS,
DAN COATS,
JUDD GREGG,
BILL FRIST,
MIKE DEWINE,
EDWARD M. KENNEDY,
CHRISTOPHER DODD,
TOM HARKIN,
BARBARA A. MIKULSKI,
Managers on the Part of the Senate.

The SPEAKER pro tempore, Mr. PETRI, recognized Mr. BLILEY and Mr. DINGELL, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said conference report?

The SPEAKER pro tempore, Mr. PETRI, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said conference report was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said conference report was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.30 ELECTIONS IN SAHARA

Mr. ROYCE moved to suspend the rules and agree to the following resolution (H. Res. 245); as amended:

Whereas United Nations Secretary General Kofi Annan appointed former United States Secretary of State James Baker III as his

Personal Envoy for Western Sahara to end the prevailing referendum stalemate;

Whereas talks between the Kingdom of Morocco and the Front for the Liberation of Saguia el Hamra and Rio de Oro (also known as the Polisario Front) mediated by Mr. Baker have achieved agreement on ways to end the referendum stalemate;

Whereas the end of the stalemate over the Western Sahara referendum would allow for the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front; and

Whereas the United States supports the holding of a free, fair, and transparent referendum on self-determination for the people of Western Sahara: Now, therefore, be it

Resolved, That the House of Representatives—

(1) expresses its full support to former United States Secretary of State James Baker III in his mission as Personal Envoy of the United Nations Secretary General for the Western Sahara;

(2) expresses its support for a referendum on self-determination for the people of Western Sahara that should meet the following criteria:

(A) free, fair, and transparent and held in the presence of international and domestic observers and international media without administrative or military pressure or interference;

(B) only genuine Sahrawis, as identified in the method agreed to by both sides, will take part in the referendum voting; and

(C) the result, once certified by the United Nations, is accepted by both sides;

(3) encourages the release of civilian political prisoners and prisoners of war held by Morocco and the Polisario Front at the earliest possible date; and

(4) requests the administration to fully support former United States Secretary of State James Baker III in his mission of organizing a free, fair, and transparent referendum on self-determination for the people of Western Sahara without military or administrative constraints.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. ROYCE and Mr. MENENDEZ, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said resolution, as amended?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said resolution, as amended, was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said resolution, as amended, was agreed to was, by unanimous consent, laid on the table.

¶130.31 FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate has passed with amendments in which the concurrence of the House is requested, A bill of the House of the following title:

H.R. 2607. An Act making appropriations for the government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 1998, and for other purposes.

The message also announced, that the Senate insists upon its amendments to the bill (H.R. 2607) ''An Act making appropriations for the government of the District of Columbia and other activities chargeable in whole or in part against the revenues of said District for the fiscal year ending September 30, 1998, and for the purposes.'', requests a conference with the House on the disagreeing votes of the two Houses thereon, and appoints Mr. STEVENS, Mr. SPECTER, Mr. DOMENICI, Mr. MCCONNELL, Mr. SHELBY, Mr. GREGG, Mr. BENNETT, Mr. CAMPBELL, Mr. FAIRCLOTH, Mrs. HUTCHISON, Mr. COCHRAN, Mr. BYRD, Mr. INOUYE, Mr. HOLLINGS, Mr. LEAHY, Mr. BUMPERS, Mr. LAUTENBERG, Mr. HARKIN, Ms. MIKULSKI, Mrs. MURRAY, and Mrs. BOXER, to be the conferees on the part of the Senate.

¶130.32 AFGHANISTAN WOMEN

Mr. ROHRABACHER moved to suspend the rules and agree to the following concurrent resolution (H. Con. Res. 156); as amended:

Whereas Congress recognizes that the legacy of civil conflict in Afghanistan during the last 17 years has had a devastating effect on the civilian population in that country, killing 2,000,000 people and displacing more than 7,000,000, and has had a particularly negative impact on the rights and security of women and girls;

Whereas the Department of State's Country Reports on Human Practices for 1996 states: ''Serious human rights violations continue to occur [. . .] political killings, torture, rape, arbitrary detention, looting, abductions and kidnappings for ransom were committed by armed units, local commanders and rogue individuals.'';

Whereas the Afghan combatants are responsible for numerous abhorrent human rights abuses, including the rape, sexual abuse, torture, abduction, and persecution of women and girls;

Whereas drug proliferation has increased in Afghanistan;

Whereas Congress is disturbed by the upsurge of reported human rights abuses in Afghanistan, including extreme restrictions placed on women and girls;

Whereas safe haven has been provided to suspected terrorists and terrorist camps may be allowed to operate in Afghanistan;

Whereas Afghanistan is a sovereign nation and must work to solve its internal disputes; and

Whereas Afghanistan and the United States recognize international human rights conventions, such as the Universal Declaration on Human Rights, which espouse respect for basic human rights of all individuals without regard to race, religion, ethnicity, or gender: Now, therefore, be it

Resolved by the House of Representatives (the Senate concurring),

SECTION 1. DECLARATION OF POLICY.

The Congress hereby—

(1) deplores the violations of international humanitarian law in Afghanistan and raises concern over the reported cases of stoning, public executions, and street beatings;

(2) condemns the targeted discrimination against women and girls and expresses deep concern regarding the prohibition of employment and education for women and girls;

(3) urges the Taliban and all other parties in Afghanistan to cease providing safe haven to suspected terrorists or permitting Afghan territory to be used for terrorist training; and

(4) takes note of the continued armed conflict in Afghanistan, affirms the need for peace negotiations and expresses hope that the Afghan parties will agree to a cease-fire throughout the country.

SEC. 2. SENSE OF THE CONGRESS.

It is the sense of Congress that the President—

(1) should continue to monitor the human rights situation in Afghanistan and should call for adherence by all factions in Afghanistan to international humanitarian law;

(2) should call for an end to the systematic discrimination and harassment of women and girls in Afghanistan;

(3) should encourage efforts to procure a durable peace in Afghanistan and should support the efforts of the United Nations Special Envoy Secretary General Lakhdar Brahimi to assist in brokering a peaceful resolution to years of conflict;

(4) should call upon all countries with influence to use their influence on the contending factions to end the fighting and come to the negotiating table, abide by internationally recognized norms of behavior, cease human rights violations, end provision of safe haven to terrorists and close terrorist training camps, and reverse discriminatory policies against women and girls;

(5) should call upon all nations to cease providing financial assistance, arms, and other kinds of support to the militaries or political organizations of any factions in Afghanistan; and

(6) should support efforts by Afghan individuals to establish a cessation of hostilities and a transitional multiparty government leading to freedom, respect for human rights, and free and fair elections.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. ROHRABACHER and Mr. LUTHER, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said concurrent resolution, as amended?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said concurrent resolution, as amended, was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said concurrent resolution, as amended, was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said concurrent resolution.

¶130.33 ERISA AMENDMENTS

Mr. FAWELL moved to suspend the rules and agree to the following amendment of the Senate to the bill (H.R. 1377) to amend title I of the Employee Retirement Income Security Act of 1974 to encourage retirement income savings:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Savings Are Vital to Everyone's Retirement Act of 1997''.

SEC. 2. FINDINGS AND PURPOSE.

(a) FINDINGS.—The Congress finds as follows:

(1) The impending retirement of the baby boom generation will severely strain our al-

ready overburdened entitlement system, necessitating increased reliance on pension and other personal savings.

(2) Studies have found that less than a third of Americans have even tried to calculate how much they will need to have saved by retirement, and that less than 20 percent are very confident they will have enough money to live comfortably throughout their retirement.

(3) A leading obstacle to expanding retirement savings is the simple fact that far too many Americans—particularly the young—are either unaware of, or without the knowledge and resources necessary to take advantage of, the extensive benefits offered by our retirement savings system.

(b) PURPOSE.—It is the purpose of this Act—

(1) to advance the public's knowledge and understanding of retirement savings and its critical importance to the future well-being of American workers and their families;

(2) to provide for a periodic, bipartisan national retirement savings summit in conjunction with the White House to elevate the issue of savings to national prominence; and

(3) to initiate the development of a broad-based, public education program to encourage and enhance individual commitment to a personal retirement savings strategy.

SEC. 3. OUTREACH BY THE DEPARTMENT OF LABOR.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131 et seq.) is amended by adding at the end the following new section:

''OUTREACH TO PROMOTE RETIREMENT INCOME SAVINGS

''SEC. 516. (a) IN GENERAL.—The Secretary shall maintain an ongoing program of outreach to the public designed to effectively promote retirement income savings by the public.

''(b) METHODS.—The Secretary shall carry out the requirements of subsection (a) by means which shall ensure effective communication to the public, including publication of public service announcements, public meetings, creation of educational materials, and establishment of a site on the Internet.

''(c) INFORMATION TO BE MADE AVAILABLE.—The information to be made available by the Secretary as part of the program of outreach required under subsection (a) shall include the following:

''(1) a description of the vehicles currently available to individuals and employers for creating and maintaining retirement income savings, specifically including information explaining to employers, in simple terms, the characteristics and operation of the different retirement savings vehicles, including the steps to establish each such vehicle, and

''(2) information regarding matters relevant to establishing retirement income savings, such as—

''(A) the forms of retirement income savings,

''(B) the concept of compound interest,

''(C) the importance of commencing savings early in life,

''(D) savings principles,

''(E) the importance of prudence and diversification in investing,

''(F) the importance of the timing of investments, and

''(G) the impact on retirement savings of life's uncertainties, such as living beyond one's life expectancy.

''(d) ESTABLISHMENT OF SITE ON THE INTERNET.—The Secretary shall establish a permanent site on the Internet concerning retirement income savings. The site shall contain at least the following information:

''(1) a means for individuals to calculate their estimated retirement savings needs, based on their retirement income goal as a percentage of their preretirement income;

''(2) a description in simple terms of the common types of retirement income savings arrangements available to both individuals and employers (specifically including small employers), including information on the amount of money that can be placed into a given vehicle, the tax treatment of the money, the amount of accumulation possible through different typical investment options and interest rate projections, and a directory of resources of more descriptive information;

''(3) materials explaining to employers in simple terms, the characteristics and operation of the different retirement savings arrangements for their workers and what the basic legal requirements are under this Act and the Internal Revenue Code of 1986, including the steps to establish each such arrangement;

''(4) copies of all educational materials developed by the Department of Labor, and by other Federal agencies in consultation with such Department, to promote retirement income savings by workers and employers; and

''(5) links to other sites maintained on the Internet by governmental agencies and nonprofit organizations that provide additional detail on retirement income savings arrangements and related topics on savings or investing.

''(e) COORDINATION.—The Secretary shall coordinate the outreach program under this section with similar efforts undertaken by other public and private entities.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended by inserting after the item relating to section 514 the following new items:

''Sec. 515. Delinquent contributions.
''Sec. 516. Outreach to promote retirement income savings.''.

SEC. 4. NATIONAL SUMMIT ON RETIREMENT SAVINGS.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 3 of this Act, is amended by adding at the end the following new section:

''NATIONAL SUMMIT ON RETIREMENT SAVINGS

''SEC. 517. (a) AUTHORITY TO CALL SUMMIT.—Not later than July 15, 1998, the President shall convene a National Summit on Retirement Income Savings at the White House, to be co-hosted by the President and the Speaker and the Minority Leader of the House of Representatives and the Majority Leader and Minority Leader of the Senate. Such a National Summit shall be convened thereafter in 2001 and 2005 on or after September 1 of each year involved. Such a National Summit shall—

''(1) advance the public's knowledge and understanding of retirement savings and its critical importance to the future well-being of American workers and their families;

''(2) facilitate the development of a broad-based, public education program to encourage and enhance individual commitment to a personal retirement savings strategy;

''(3) develop recommendations for additional research, reforms, and actions in the field of private pensions and individual retirement savings; and

''(4) disseminate the report of, and information obtained by, the National Summit and exhibit materials and works of the National Summit.

''(b) PLANNING AND DIRECTION.—The National Summit shall be planned and conducted under the direction of the Secretary, in consultation with, and with the assistance of, the heads of such other Federal departments and agencies as the President may designate. Such assistance may include the assignment of personnel. The Secretary shall, in planning and conducting the National Summit, consult with the congressional leaders specified in subsection (e)(2). The Secretary shall also, in carrying out the Secretary's duties under this subsection, consult and coordinate with at least one organization made up of private sector businesses and associations partnered with Government entities to promote long-term financial security in retirement through savings.

''(c) PURPOSE OF NATIONAL SUMMIT.—The purpose of the National Summit shall be—

''(1) to increase the public awareness of the value of personal savings for retirement;

''(2) to advance the public's knowledge and understanding of retirement savings and its critical importance to the future well-being of American workers and their families;

''(3) to facilitate the development of a broad-based, public education program to encourage and enhance individual commitment to a personal retirement savings strategy;

''(4) to identify the problems workers have in setting aside adequate savings for retirement;

''(5) to identify the barriers which employers, especially small employers, face in assisting their workers in accumulating retirement savings;

''(6) to examine the impact and effectiveness of individual employers to promote personal savings for retirement among their workers and to promote participation in company savings options;

''(7) to examine the impact and effectiveness of government programs at the Federal, State, and local levels to educate the public about, and to encourage, retirement income savings;

''(8) to develop such specific and comprehensive recommendations for the legislative and executive branches of the Government and for private sector action as may be appropriate for promoting private pensions and individual retirement savings; and

''(9) to develop recommendations for the coordination of Federal, State, and local retirement income savings initiatives among the Federal, State, and local levels of government and for the coordination of such initiatives.

''(d) SCOPE OF NATIONAL SUMMIT.—The scope of the National Summit shall consist of issues relating to individual and employer-based retirement savings and shall not include issues relating to the old-age, survivors, and disability insurance program under title II of the Social Security Act.

''(e) NATIONAL SUMMIT PARTICIPANTS.—

''(1) IN GENERAL.—To carry out the purposes of the National Summit, the National Summit shall bring together—

''(A) professionals and other individuals working in the fields of employee benefits and retirement savings;

''(B) Members of Congress and officials in the executive branch;

''(C) representatives of State and local governments;

''(D) representatives of private sector institutions, including individual employers, concerned about promoting the issue of retirement savings and facilitating savings among American workers; and

''(E) representatives of the general public.

''(2) STATUTORILY REQUIRED PARTICIPATION.—The participants in the National Summit shall include the following individuals or their designees:

''(A) the Speaker and the Minority Leader of the House of Representatives;

''(B) the Majority Leader and the Minority Leader of the Senate;

''(C) the Chairman and ranking Member of the Committee on Education and the Workforce of the House of Representatives;

''(D) the Chairman and ranking Member of the Committee on Labor and Human Resources of the Senate;

''(E) the Chairman and ranking Member of the Special Committee on Aging of the Senate;

''(F) the Chairman and ranking Member of the Subcommittees on Labor, Health and Human Services, and Education of the Senate and House of Representatives; and

''(G) the parties referred to in subsection (b).

''(3) ADDITIONAL PARTICIPANTS.—

''(A) IN GENERAL.—There shall be not more than 200 additional participants. Of such additional participants—

''(i) one-half shall be appointed by the President, in consultation with the elected leaders of the President's party in Congress (either the Speaker of the House of Representatives or the Minority Leader of the House of Representatives, and either the Majority Leader or the Minority Leader of the Senate; and

''(ii) one-half shall be appointed by the elected leaders of Congress of the party to which the President does not belong (one-half of that allotment to be appointed by either the Speaker of the House of Representatives or the Minority Leader of the House of Representatives, and one-half of that allotment to be appointed by either the Majority Leader or the Minority Leader of the Senate).

''(B) APPOINTMENT REQUIREMENTS.—The additional participants described in subparagraph (A) shall be—

''(i) appointed not later than January 31, 1998;

''(ii) selected without regard to political affiliation or past partisan activity; and

''(iii) representative of the diversity of thought in the fields of employee benefits and retirement income savings.

''(4) PRESIDING OFFICERS.—The National Summit shall be presided over equally by representatives of the executive and legislative branches.

''(f) NATIONAL SUMMIT ADMINISTRATION.—

''(1) ADMINISTRATION.—In administering this section, the Secretary shall—

''(A) request the cooperation and assistance of such other Federal departments and agencies and other parties referred to in subsection (b) as may be appropriate in the carrying out of this section;

''(B) furnish all reasonable assistance to State agencies, area agencies, and other appropriate organizations to enable them to organize and conduct conferences in conjunction with the National Summit;

''(C) make available for public comment a proposed agenda for the National Summit that reflects to the greatest extent possible the purposes for the National Summit set out in this section;

''(D) prepare and make available background materials for the use of participants in the National Summit that the Secretary considers necessary; and

''(E) appoint and fix the pay of such additional personnel as may be necessary to carry out the provisions of this section without regard to provisions of title 5, United States Code, governing appointments in the competitive service, and without regard to chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

''(2) DUTIES.—The Secretary shall, in carrying out the responsibilities and functions of the Secretary under this section, and as part of the National Summit, ensure that—

''(A) the National Summit shall be conducted in a manner that ensures broad participation of Federal, State, and local agencies and private organizations, professionals, and others involved in retirement income savings and provides a strong basis for assistance to be provided under paragraph (1)(B);

''(B) the agenda prepared under paragraph (1)(C) for the National Summit is published in the Federal Register; and

''(C) the personnel appointed under paragraph (1)(E) shall be fairly balanced in terms of points of views represented and shall be appointed without regard to political affiliation or previous partisan activities.

''(3) NONAPPLICATION OF FACA.—The provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the National Summit.

''(g) REPORT.—The Secretary shall prepare a report describing the activities of the National Summit and shall submit the report to the President, the Speaker and Minority Leader of the House of Representatives, the Majority and Minority Leaders of the Senate, and the chief executive officers of the States not later than 90 days after the date on which the National Summit is adjourned.

''(h) DEFINITION.—For purposes of this section, the term 'State' means a State, the District of Columbia, the Commonwealth of Puerto Rico, the Commonwealth of the Northern Mariana Islands, Guam, the Virgin Islands, American Samoa, and any other territory or possession of the United States.

''(i) AUTHORIZATION OF APPROPRIATIONS.—

''(1) IN GENERAL.—There is authorized to be appropriated for fiscal years beginning on or after October 1, 1997, such sums as are necessary to carry out this section.

''(2) AUTHORIZATION TO ACCEPT PRIVATE CONTRIBUTIONS.—In order to facilitate the National Summit as a public-private partnership, the Secretary may accept private contributions, in the form of money, supplies, or services, to defray the costs of the National Summit.

''(j) FINANCIAL OBLIGATION FOR FISCAL YEAR 1998.—The financial obligation for the Department of Labor for fiscal year 1998 shall not exceed the lesser of—

''(1) one-half of the costs of the National Summit; or

''(2) $250,000.

The private sector organization described in subsection (b) and contracted with by the Secretary shall be obligated for the balance of the cost of the National Summit.

''(k) CONTRACTS.—The Secretary may enter into contracts to carry out the Secretary's responsibilities under this section. The Secretary shall enter into a contract on a sole-source basis to ensure the timely completion of the National Summit in fiscal year 1998.''.

(b) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act, as amended by section 3 of this Act, is amended by inserting after the item relating to section 516 the following new item:

''Sec. 517. National Summit on Retirement Savings.''.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. FAWELL and Mr. PAYNE, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said amendment?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said amendment was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said amendment was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.34 FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate had passed without amendment a joint resolution of the House of the following title:

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

The message also announced that the Senate had passed a bill of the following title, in which the concurrence of the House is requested:

S. 1502. An Act entitled the ''District of Columbia Student Opportunity Scholarship Act of 1997''.

¶130.35 U.S. FIRE ADMINISTRATION AUTHORIZATION

Mr. SENSENBRENNER moved to suspend the rules and pass the bill of the Senate (S. 1231) to authorize appropriations for fiscal years 1998 and 1999 for the United States Fire Administration, and for other purposes.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. SENSENBRENNER and Mr. BARCIA, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.36 LAND CONVEYANCE TO STANISLAUS COUNTY, CALIFORNIA

Mr. SENSENBRENNER moved to suspend the rules and pass the bill (H.R. 112) to provide for the conveyance of certain property from the United States to Stanislaus County, California.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. SENSENBRENNER and Mr. CRAMER, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.37 AUBURN INDIAN RESTORATION

Mr. DOOLITTLE moved to suspend the rules and pass the bill (H.R. 1805) to amend the Auburn Indian Restoration Act to establish restrictions related to gaming on and use of land held in trust for the United Auburn Indian Community of the Auburn Racheria of California, and for other purposes.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. DOOLITTLE for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.38 WATER-RELATED TECHNICAL CORRECTIONS

Mr. DOOLITTLE moved to suspend the rules and pass the bill (H.R. 2402) to make technical and clarifying amendments to improve management of water-related facilities in the Western United States; as amended.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. DOOLITTLE for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. LAZIO, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill, as amended, was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.39 JIMMY CARTER NATIONAL HISTORIC SITE

Mr. HANSEN moved to suspend the rules and pass the bill of the Senate (S. 669) to provide for the acquisition of the Plains Railroad Depot as the Jimmy Carter National Historic Site.

The SPEAKER pro tempore, Mr. LAZIO, recognized Mr. HANSEN and Mr. BISHOP, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.40 ARCHES NATIONAL PARK EXPANSION

Mr. HANSEN moved to suspend the rules and pass the bill (H.R. 2283) to expand the boundaries of Arches National Park in the State of Utah to include portions of the following drainages, Salt Wash, Lost Spring Canyon, Fish Sheep Draw, Clover Canyon, Cordova Canyon, Mine Draw, and Cottonwood Wash, which are currently under the jurisdiction of the Bureau of Land Management, and to include a portion of Fish Sheep Draw, which is currently owned by the State of Utah; as amended.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. HANSEN for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

By unanimous consent, the title was amended so as to read: ''An Act to expand the boundaries of Arches National Park in the State of Utah to include portions of the following drainages: Salt Wash, Lost Spring Canyon, Fish Sheep Draw, Clover Canyon, Cordova Canyon, Mine Draw, and Cottonwood Wash, which are currently under the jurisdiction of the Bureau of Land Management, and to include a portion of Fish Sheep Draw, which is currently owned by the State of Utah.''.

A motion to reconsider the votes whereby the rules were suspended and said bill, as amended, was passed and the title was amended was, by unanimous consent, laid on the table.

¶130.41 JAMES L. FOREMAN U.S. COURTHOUSE

Mr. DUNCAN moved to suspend the rules and pass the bill (H.R. 1502) to designate the United States Courthouse located at 301 West Main Street in Benton, Illinois, as the ''James L. Foreman United States Courthouse''.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. DUNCAN and Mr. TRAFICANT, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.42 UNIFORM RELOCATION ASSISTANCE TO ALIENS

Mr. KIM moved to suspend the rules and pass the bill of the Senate (S. 1258) to amend the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 to prohibit an alien who is not lawfully present in the United States from receiving assistance under that Act.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. KIM and Mr. TRAFICANT, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.43 CLEVELAND AIRPORT TRANSFER

Mr. DUNCAN moved to suspend the rules and pass the bill of the Senate (S. 1347) to permit the city of Cleveland, Ohio, to convey certain lands that the United States conveyed to the city.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. DUNCAN and Mr. LIPINSKI, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.44 SUSPENSION OF THE RULES NOTICE

Mr. LATOURETTE, pursuant to section 2 of House Resolution 305, at 10:40

p.m. announced the Speaker will recognize Members for motions to suspend the rules under clause 2 of rule XXVII, with respect to the following bills and resolutions that may be considered today: H.R. 2977, National Academy of Sciences and National Academy of Public Administration Public Disclosure Requirements; S.1378, U.S. Mail Use for Missing Children; S. Con. Res. 61, Printing of ''Our Flag''; S. Con. Res. 62, Printing of ''How Our Laws Are Made''; S. Con. Res. 63, Printing of ''The Constitution of the United States of America''; H.R. 2979, Library of Congress Land Acquisition; H.R. 764, Bankruptcy Amendments of 1997; H.R. 2440, Title 9, U.S. Code, Section 10 Amendments; H.J. Res. 95, Chickasaw Trail Economic Development Compact; H.J. Res. 96, Washington Metropolitan Area Transit Regulation Compact; S. 1079, Ft. Berthold Indiana Reservation Mineral Leasing; and H.R. 1604, Ottawa and Chippewa Indians Judgment Funds.

¶130.45 PILOT RECORDS IMPROVEMENT

Mr. DUNCAN moved to suspend the rules and pass the bill (H.R. 2626) to make clarifications to the Pilot Records Improvement Act of 1996, and for other purposes; as amended.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. DUNCAN and Mr. LIPINSKI, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill, as amended, was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.46 SUSPENSION OF THE RULES NOTICE

Mr. LATOURETTE, pursuant to section 2 of House Resolution 305, at 11:00 p.m. announced the Speaker will recognize Members for motions to suspend the rules under clause 2 of rule XXVII, with respect to the following bill that may be considered today: H.R. 765, Shackleford Banks Wild Horses Protection Act.

¶130.47 FAMILIES AFFECTED BY FOREIGN AIR CARRIER ACCIDENTS

Mr. DUNCAN moved to suspend the rules and pass the bill (H.R. 2476) to amend title 49, United States Code, to require the National Transportation Safety Board and individual foreign air carriers to address the needs of families of passengers involved in aircraft accidents involving foreign air carriers; as amended.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. DUNCAN and Mr. LIPINSKI, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill, as amended?

The SPEAKER pro tempore, Mr. CALLAHAN, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill, as amended, was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill, as amended, was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.48 EXPORT-IMPORT BANK REAUTHORIZATION

Mr. CASTLE moved to suspend the rules and agree to the following conference report (Rept. No. 105–392):

The committee of conference on the disagreeing votes of the two Houses on the amendment of the House to the bill (S. 1026), to reauthorize the Export-Import Bank of the United States, having met, after full and free conference, have agreed to recommend and do recommend to their respective Houses as follows:

That the Senate recede from its disagreement to the amendment of the House and agree to the same with an amendment as follows:

In lieu of the matter proposed to be inserted by the House amendment, insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Export-Import Bank Reauthorization Act of 1997''.

(b) TABLE OF CONTENTS.—

SEC. 2. EXTENSION OF AUTHORITY.

(a) IN GENERAL.—Section 7 of the Export-Import Bank Act of 1945 (12 U.S.C. 635f) is amended by striking ''until'' and all that follows through the end period and inserting ''until the close of business on September 30, 2001.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect on September 30, 1997.

SEC. 3. TIED AID CREDIT FUND AUTHORITY.

(a) EXPENDITURES FROM FUND.—Section 10(c)(2) of the Export-Import Bank Act of 1945 (12 U.S.C. 635i–3(c)(2)) is amended by striking ''through'' and all that follows through ''1997''.

(b) AUTHORIZATION.—Section 10(e) of such Act (12 U.S.C. 635i–3(e)) is amended by striking the first sentence and inserting the following: ''There are authorized to be appropriated to the Fund such sums as may be necessary to carry out the purposes of this section.''.

SEC. 4. EXTENSION OF AUTHORITY TO PROVIDE FINANCING FOR THE EXPORT OF NONLETHAL DEFENSE ARTICLES OR SERVICES THE PRIMARY END USE OF WHICH WILL BE FOR CIVILIAN PURPOSES.

Section 1(c) of Public Law 103–428 (12 U.S.C. 635 note; 108 Stat. 4376) is amended by striking ''1997'' and inserting ''2001''.

SEC. 5. CLARIFICATION OF PROCEDURES FOR DENYING CREDIT BASED ON THE NATIONAL INTEREST.

Section 2(b)(1)(B) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)(1)(B)) is amended—

(1) in the last sentence, by inserting '', after consultation with the Committee on Banking and Financial Services of the House of Representatives and the Committee on Banking, Housing, and Urban Affairs of the Senate,'' after ''President''; and

(2) by adding at the end the following: ''Each such determination shall be delivered in writing to the President of the Bank, shall state that the determination is made pursuant to this section, and shall specify the applications or categories of applications for credit which should be denied by the Bank in furtherance of the national interest.''.

SEC. 6. ADMINISTRATIVE COUNSEL.

Section 3(e) of the Export-Import Bank Act of 1945 (12 U.S.C. 635a(e)) is amended—

(1) by inserting ''(1)'' after ''(e)''; and

(2) by adding at the end the following:

''(2) The General Counsel of the Bank shall ensure that the directors, officers, and employees of the Bank have available appropriate legal counsel for advice on, and oversight of, issues relating to personnel matters and other administrative law matters by designating an attorney to serve as Assistant General Counsel for Administration, whose duties, under the supervision of the General Counsel, shall be concerned solely or primarily with such issues.''.

SEC. 7. ADVISORY COMMITTEE FOR SUB-SAHARAN AFRICA.

(a) IN GENERAL.—Section 2(b) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)) is amended by inserting after paragraph (8) the following:

''(9)(A) The Board of Directors of the Bank shall take prompt measures, consistent with the credit standards otherwise required by law, to promote the expansion of the Bank's financial commitments in sub-Saharan Africa under the loan, guarantee, and insurance programs of the Bank.

''(B)(i) The Board of Directors shall establish and use an advisory committee to advise the Board of Directors on the development and implementation of policies and programs designed to support the expansion described in subparagraph (A).

''(ii) The advisory committee shall make recommendations to the Board of Directors on how the Bank can facilitate greater support by United States commercial banks for trade with sub-Saharan Africa.

''(iii) The advisory committee shall terminate 4 years after the date of enactment of this subparagraph.''.

(b) REPORTS TO CONGRESS.—Within 6 months after the date of enactment of this Act, and annually for each of the 4 years thereafter, the Board of Directors of the Ex-

port-Import Bank of the United States shall submit to Congress a report on the steps that the Board has taken to implement section 2(b)(9)(B) of the Export-Import Bank Act of 1945 and any recommendations of the advisory committee established pursuant to such section.

SEC. 8. INCREASE IN LABOR REPRESENTATION ON THE ADVISORY COMMITTEE OF THE EXPORT-IMPORT BANK.

Section 3(d)(2) of the Export-Import Bank Act of 1945 (12 U.S.C. 635a(d)(2)) is amended—

(1) by inserting ''(A)'' after ''(2)''; and

(2) by adding at the end the following:

''(B) Not less than 2 members appointed to the Advisory Committee shall be representative of the labor community, except that no 2 representatives of the labor community shall be selected from the same labor union.''.

SEC. 9. OUTREACH TO COMPANIES.

Section 2(b)(1) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)(1)) is amended by adding at the end the following:

''(I) The President of the Bank shall undertake efforts to enhance the Bank's capacity to provide information about the Bank's programs to small and rural companies which have not previously participated in the Bank's programs. Not later than 1 year after the date of enactment of this subparagraph, the President of the Bank shall submit to Congress a report on the activities undertaken pursuant to this subparagraph.''.

SEC. 10. CLARIFICATION OF THE OBJECTIVES OF THE EXPORT-IMPORT BANK.

Section 2(b)(1)(A) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)(1)(A)) is amended in the first sentence by striking ''real income'' and all that follows to the end period and inserting: ''real income, a commitment to reinvestment and job creation, and the increased development of the productive resources of the United States''.

SEC. 11. INCLUDING CHILD LABOR AS A CRITERION FOR DENYING CREDIT BASED ON THE NATIONAL INTEREST.

Section 2(b)(1)(B) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)(1)(B)), as amended by section 5, is amended in the next to the last sentence by inserting ''(including child labor)'' after ''human rights''.

SEC. 12. PROHIBITION RELATING TO RUSSIAN TRANSFERS OF CERTAIN MISSILES TO THE PEOPLE'S REPUBLIC OF CHINA.

Section 2(b) of the Export-Import Bank Act of 1945 (12 U.S.C. 635(b)) is amended by adding at the end the following:

''(12) PROHIBITION RELATING TO RUSSIAN TRANSFERS OF CERTAIN MISSILE SYSTEMS.—If the President of the United States determines that the military or Government of the Russian Federation has transferred or delivered to the People's Republic of China an SS–N–22 missile system and that the transfer or delivery represents a significant and imminent threat to the security of the United States, the President of the United States shall notify the Bank of the transfer or delivery as soon as practicable. Upon receipt of the notice and if so directed by the President of the United States, the Board of Directors of the Bank shall not give approval to guarantee, insure, extend credit, or participate in the extension of credit in connection with the purchase of any good or service by the military or Government of the Russian Federation.''.

And the House agrees to the same.

JAMES A. LEACH,
MICHAEL N. CASTLE,
DOUGLAS BEREUTER,
JOHN J. LAFALCE,
FLOYD H. FLAKE,
Managers on the Part of the House.

ALFONSE D'AMATO,
ROD GRAMS,
CHUCK HAGEL,
PAUL SARBANES,
CAROL MOSELY-BRAUN,
Managers on the Part of the Senate.

The SPEAKER pro tempore, Mr. CALLAHAN, recognized Mr. CASTLE and Mr. FLAKE, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said conference report?

The SPEAKER pro tempore, Mr. EVERETT, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said conference report was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said conference report was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.49 EPCA PROGRAMS EXTENSIONS

Mr. DAN SCHAEFER of Colorado moved to suspend the rules and agree to the following resolution (H. Res. 317):

Resolved, That, upon the adoption of this resolution, the bill H.R. 2472, to extend certain programs under the Energy Policy and Conservation Act, be, and the same is hereby, taken from the Speaker's table to the end that the Senate amendment to the text of the bill be, and the same is hereby, agreed to with an amendment as follows: In lieu of the matter proposed to be inserted by the Senate, insert the following:

SECTION 1. ENERGY POLICY AND CONSERVATION ACT AMENDMENTS.

The Energy Policy and Conservation Act is amended—

(1) in section 166 (42 U.S.C. 6246) by striking ''1997'' and inserting in lieu thereof ''1998'';

(2) in section 181 (42 U.S.C. 6251) by striking ''September 30, 1997'' both places it appears and inserting in lieu thereof ''September 1, 1998''; and

(3) in section 281 (42 U.S.C. 6285) by striking ''September 30, 1997'' both places it appears and inserting in lieu thereof ''September 1, 1998''.

The SPEAKER pro tempore, Mr. EVERETT, recognized Mr. DAN SCHAEFER of Colorado and Mr. HALL of Texas, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and agree to said resolution?

The SPEAKER pro tempore, Mr. EVERETT, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said resolution was agreed to.

A motion to reconsider the vote whereby the rules were suspended and said resolution was agreed to was, by unanimous consent, laid on the table.

Ordered, That the Clerk notify the Senate thereof.

¶130.50 FURTHER MESSAGE FROM THE SENATE

A further message from the Senate by Mr. Lundregan, one of its clerks, announced that the Senate had passed bills of the following titles, in which the concurrence of the House is requested:

S. 1189. An Act to increase the criminal penalties for assaulting or threatening Federal judges, their family members, and other public servants, and for other purposes.

S. 1228. An Act to provide for a 10-year circulating commemorative coin program to commemorate each of the 50 States, and for other purposes.

S. 1507. An Act to amend the National Defense Authorization Act for Fiscal Year 1998 to make certain technical corrections.

¶130.51 PROVIDING FOR THE CONSIDERATION OF S. 738

Mr. DIAZ-BALART, by direction of the Committee on Rules, reported (Rept. No. 105–400) the resolution (H. Res. 319) providing for consideration of the bill of the Senate (S. 738) to reform the statutes relating to Amtrak, to authorize appropriations for Amtrak, and for other purposes.

When said resolution and report were referred to the House Calendar and ordered printed.

¶130.52 IMMIGRANT ENTRY-EXIT CONTROL SYSTEM

Mr. SMITH of Texas moved to suspend the rules and pass the bill (H.R. 2920) to amend the Illegal Immigration Reform and Immigrant Responsibility Act of 1996 to modify the requirements for implementation of an entry-exit control system.

The SPEAKER pro tempore, Mr. EVERETT, recognized Mr. SMITH of Texas and Mr. CONYERS, each for 20 minutes.

MONDAY, NOVEMBER 10 (LEGISLATIVE DAY OF NOVEMBER 9), 1997

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. PEASE, announced that two-thirds of the Members present had voted in the affirmative.

Mr. WATT of North Carolina objected to the vote on the ground that a quorum was not present and not voting.

A quorum not being present,

The roll was called under clause 4, rule XV, and the call was taken by electronic device.

When there appeared { Yeas ..... 325 / Nays 90

¶130.53 [Roll No. 627]

YEAS—325

Ackerman	Baker	Bartlett
Aderholt	Baldacci	Barton
Allen	Ballenger	Bass
Andrews	Barcia	Bateman
Archer	Barr	Bereuter
Armey	Barrett (NE)	Berman
Bachus	Barrett (WI)	Bilirakis

Blagojevich
Bliley
Blumenauer
Blunt
Boehlert
Boehner
Bonilla
Bonior
Bono
Borski
Boswell
Boyd
Brady
Brown (OH)
Bryant
Bunning
Burr
Buyer
Callahan
Calvert
Camp
Campbell
Canady
Cannon
Cardin
Castle
Chabot
Chambliss
Chenoweth
Christensen
Clement
Coble
Collins
Combest
Condit
Cook
Cooksey
Costello
Cox
Coyne
Cramer
Crane
Crapo
Cunningham
Danner
Davis (FL)
Davis (VA)
DeFazio
DeGette
Delahunt
DeLauro
DeLay
Deutsch
Diaz-Balart
Dickey
Dicks
Dixon
Doolittle
Doyle
Dreier
Duncan
Dunn
Ehlers
Ehrlich
Emerson
Engel
English
Ensign
Eshoo
Everett
Farr
Fawell
Fazio
Foley
Forbes
Fossella
Fowler
Fox
Frank (MA)
Franks (NJ)
Frelinghuysen
Furse
Gallegly
Ganske
Gejdenson
Gekas
Gephardt
Gibbons
Gilchrest
Gillmor
Gilman
Goode
Goodlatte
Goodling
Gordon
Goss
Graham
Granger
Greenwood
Gutknecht
Hall (OH)
Hall (TX)
Hamilton
Hansen
Hastert
Hastings (WA)
Hayworth
Hefley
Herger
Hill
Hilleary
Hinchey
Hobson
Hoekstra
Holden
Hooley
Horn
Hostettler
Houghton
Hoyer
Hulshof
Hutchinson
Hyde
Inglis
Istook
Jenkins
John
Johnson (CT)
Johnson (WI)
Jones
Kanjorski
Kaptur
Kasich
Kelly
Kennedy (MA)
Kennelly
Kildee
Kilpatrick
Kim
Kind (WI)
King (NY)
Kingston
Klink
Knollenberg
Kolbe
Kucinich
LaFalce
LaHood
Lampson
Latham
LaTourette
Lazio
Leach
Levin
Lewis (CA)
Lewis (KY)
Linder
Lipinski
Livingston
Lofgren
Lowey
Lucas
Luther
Maloney (CT)
Maloney (NY)
Manton
Manzullo
Markey
Mascara
McCarthy (MO)
McCarthy (NY)
McCollum
McDade
McGovern
McHale
McHugh
McInnis
McIntosh
McIntyre
McKeon
McNulty
Meehan
Menendez
Metcalf
Mica
Miller (FL)
Minge
Moakley
Mollohan
Moran (KS)
Moran (VA)
Morella
Murtha
Myrick
Nadler
Neal
Nethercutt
Neumann
Ney
Northup
Nussle
Oberstar
Obey
Olver
Oxley
Packard
Pallone
Pappas
Parker
Pascrell
Paul
Paxon
Pease
Peterson (MN)
Peterson (PA)
Petri
Pickering
Pickett
Pitts
Pombo
Pomeroy
Porter
Portman
Poshard
Pryce (OH)
Quinn
Radanovich
Rahall
Ramstad
Redmond
Regula
Riggs
Rivers
Roemer
Rogan
Rogers
Ros-Lehtinen
Royce
Ryun
Sabo
Sanders
Sanford
Sawyer
Saxton
Schaefer, Dan
Schumer
Sensenbrenner
Sessions
Shaw
Shays
Shimkus
Shuster
Sisisky
Skaggs
Slaughter
Smith (MI)
Smith (NJ)
Smith (OR)
Smith (TX)
Smith, Adam
Smith, Linda
Snowbarger
Solomon
Souder
Spence
Spratt
Stabenow
Stearns
Stump
Stupak
Sununu
Talent
Tanner
Tauscher
Tauzin
Taylor (NC)
Thomas
Thornberry
Thune
Thurman
Tiahrt
Tierney
Towns
Upton
Vento
Visclosky
Walsh
Wamp
Watkins
Watts (OK)
Waxman
Weldon (FL)
Weldon (PA)
Weller
Wexler
Weygand
White
Whitfield
Wicker
Wise
Wolf
Woolsey
Young (AK)
Young (FL)

NAYS—90

Abercrombie
Baesler
Becerra
Bentsen
Berry
Bilbray
Bishop
Brown (CA)
Brown (FL)
Carson
Clay
Clayton
Clyburn
Coburn
Conyers
Cummings
Davis (IL)
Deal
Dellums
Doggett
Dooley
Edwards
Etheridge
Evans
Fattah
Filner
Ford
Frost
Green
Gutierrez
Harman
Hastings (FL)
Hefner
Hilliard
Hinojosa
Hunter
Jackson (IL)
Jackson-Lee (TX)
Jefferson
Johnson, E. B.
Kennedy (RI)
Kleczka
Lantos
Lewis (GA)
LoBiondo
Martinez
Matsui
McKinney
Meek
Millender-McDonald
Miller (CA)
Mink
Ortiz
Owens
Pastor
Payne
Pelosi
Price (NC)
Rangel
Reyes
Rodriguez
Rohrabacher
Rothman
Roybal-Allard
Rush
Salmon
Sanchez
Sandlin
Scarborough
Schaffer, Bob
Scott
Serrano
Shadegg
Sherman
Skeen
Skelton
Snyder
Stark
Stenholm
Stokes
Strickland
Taylor (MS)
Thompson
Torres
Traficant
Turner
Velazquez
Waters
Watt (NC)
Wynn

NOT VOTING—18

Boucher
Burton
Cubin
Dingell
Ewing
Flake
Foglietta
Gonzalez
Johnson, Sam
Klug
Largent
McCrery
McDermott
Norwood
Riley
Roukema
Schiff
Yates

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.54 UNFINISHED BUSINESS—APPROVAL OF THE JOURNAL

The SPEAKER pro tempore, Mr. PEASE, pursuant to clause 5, rule I, announced the unfinished business to be the question on agreeing to the Chair's approval of the Journal of Saturday, November 8, 1997.

The question being put, viva voce,

Will the House agree to the Chair's approval of said Journal?

The SPEAKER pro tempore, Mr. PEASE, announced that the yeas had it.

So the Journal was approved.

¶130.55 PROVIDING FOR THE CONSIDERATION OF CERTAIN RESOLUTIONS IN PREPARATION FOR THE ADJOURNMENT SINE DIE

Ms. PRYCE, by direction of the Committee on Rules, called up the following resolution (H. Res. 311):

Resolved, That upon the adoption of this resolution it shall be in order to consider in the House a joint resolution waiving certain enrollment requirements with respect to certain specified bills of the One Hundred Fifth Congress. The joint resolution shall be considered as read for amendment. The previous question shall be considered as ordered on the joint resolution to final passage without intervening motion except: (1) One hour of debate equally divided and controlled by the majority leader and the minority leader or their designees; and (2) one motion to commit.

SEC. 2. Upon the adoption of this resolution it shall be in order to consider in the House a joint resolution appointing the day for the convening of the second session of the One Hundred Fifth Congress. The joint resolution shall be considered as read for amendment. The previous question shall be considered as ordered on the joint resolution to final passage without intervening motion except: (1) One hour of debate equally divided and controlled by the majority leader and the minority leader or their designees; and (2) one motion to commit.

SEC. 3. The Speaker, the majority leader, and the minority leader may accept resignations and make appointments to commissions, boards, and committees following the adjournment of the first session sine die as authorized by law or by the House.

SEC. 4. A resolution providing that a committee of two Members of the House be appointed to wait upon the President of the United States and inform him that the House of Representatives has completed its business of the session and is ready to adjourn, unless the President has some other communication to make to them, is hereby adopted.

SEC. 5. A concurrent resolution providing that the two Houses of Congress assemble in the Hall of the House of Representatives on Tuesday, January 27, 1998, at 9 p.m., for the purpose of receiving such communication as the President of the United States shall be pleased to make to them is hereby adopted.

SEC. 6. House Resolution 306 is laid on the table.

When said resolution was considered.

After debate,

On motion of Ms. PRYCE, the previous question was ordered on the resolution to its adoption or rejection.

The question being put, viva voce,

Will the House agree to said resolution?

The SPEAKER pro tempore, Mr. PEASE, announced that the yeas had it.

Mr. SOLOMON demanded that the vote be taken by the yeas and nays, whcih demand was supported by one-fifth of the Members present, so the years and nays were ordered.

The vote was taken by electronic device.

It was decided in the affirmative ..... { Yeas ..... 257 / Nays 159

¶130.56 [Roll No. 628]

YEAS—257

Aderholt
Allen
Archer
Armey
Bachus
Baker
Ballenger
Barcia
Barr
Barrett (NE)
Barrett (WI)
Bartlett
Bass
Bateman
Bereuter
Bilbray
Bilirakis
Blagojevich
Bliley
Blunt
Boehlert
Boehner
Bonilla
Bono
Brady
Bryant
Bunning
Burr
Buyer
Callahan
Calvert
Camp
Campbell
Canady
Cannon
Castle
Chabot
Chambliss
Chenoweth
Christensen
Clement
Coble
Coburn
Collins
Combest
Cook
Cooksey
Cox
Cramer
Crane
Crapo
Cunningham
Danner
Davis (FL)
Davis (VA)
Deal
Delahunt
DeLay
Dellums
Diaz-Balart
Dickey
Dicks
Dixon
Doolittle
Dreier
Duncan
Dunn
Ehlers
Ehrlich
Emerson
English
Ensign
Everett
Ewing
Fawell
Foley
Forbes
Fossella

Fowler	Largent	Rangel
Fox	Latham	Redmond
Frank (MA)	LaTourette	Regula
Franks (NJ)	Lazio	Riggs
Frelinghuysen	Leach	Rogan
Frost	Lewis (CA)	Rogers
Gallegly	Lewis (KY)	Rohrabacher
Ganske	Linder	Ros-Lehtinen
Gekas	Lipinski	Royce
Gibbons	Livingston	Ryun
Gilchrest	LoBiondo	Sabo
Gillmor	Lucas	Sanford
Gilman	Maloney (CT)	Sawyer
Goodlatte	Manzullo	Saxton
Gordon	McCarthy (NY)	Schaefer, Dan
Goss	McCollum	Schaffer, Bob
Graham	McDade	Sensenbrenner
Granger	McGovern	Sessions
Greenwood	McHugh	Shadegg
Gutknecht	McInnis	Shaw
Hall (OH)	McIntosh	Shimkus
Hall (TX)	McIntyre	Shuster
Hansen	McKeon	Skeen
Hastert	McKinney	Smith (MI)
Hastings (WA)	Metcalf	Smith (NJ)
Hayworth	Mica	Smith (TX)
Hefley	Miller (FL)	Smith, Adam
Herger	Minge	Smith, Linda
Hill	Moakley	Snowbarger
Hilleary	Moran (KS)	Solomon
Hobson	Morella	Souder
Hoekstra	Myrick	Spence
Horn	Nethercutt	Stabenow
Hostettler	Neumann	Stearns
Houghton	Ney	Stokes
Hulshof	Northup	Stump
Hunter	Norwood	Sununu
Hutchinson	Nussle	Talent
Hyde	Oxley	Tauzin
Inglis	Packard	Taylor (NC)
Istook	Pappas	Thomas
Jackson (IL)	Parker	Thornberry
Jefferson	Pascrell	Thune
Jenkins	Pastor	Tiahrt
John	Paul	Traficant
Johnson (CT)	Paxon	Upton
Johnson, Sam	Pease	Walsh
Jones	Pelosi	Watkins
Kasich	Peterson (PA)	Watts (OK)
Kelly	Petri	Weldon (FL)
Kennedy (MA)	Pickering	Weldon (PA)
Kennelly	Pitts	Weller
Kildee	Pombo	White
Kim	Pomeroy	Whitfield
King (NY)	Porter	Wicker
Kingston	Portman	Wolf
Knollenberg	Pryce (OH)	Wynn
Kolbe	Quinn	Young (AK)
LaHood	Radanovich	Young (FL)
Lantos	Ramstad	

NAYS—159

Abercrombie	Engel	Lampson
Ackerman	Eshoo	Levin
Andrews	Etheridge	Lewis (GA)
Baesler	Evans	Lofgren
Baldacci	Farr	Lowey
Becerra	Fattah	Luther
Bentsen	Fazio	Maloney (NY)
Berman	Filner	Manton
Berry	Ford	Markey
Bishop	Furse	Mascara
Blumenauer	Gejdenson	Matsui
Bonior	Gephardt	McCarthy (MO)
Borski	Goode	McHale
Boswell	Green	McNulty
Boucher	Gutierrez	Meehan
Boyd	Hamilton	Meek
Brown (CA)	Harman	Menendez
Brown (FL)	Hastings (FL)	Millender-McDonald
Brown (OH)	Hefner	Miller (CA)
Cardin	Hilliard	Mink
Carson	Hinchey	Mollohan
Clay	Hinojosa	Moran (VA)
Clayton	Holden	Nadler
Clyburn	Hooley	Neal
Condit	Hoyer	Oberstar
Conyers	Jackson-Lee (TX)	Obey
Costello	Johnson (WI)	Olver
Coyne	Johnson, E. B.	Ortiz
Cummings	Kanjorski	Owens
Davis (IL)	Kaptur	Pallone
DeFazio	Kennedy (RI)	Payne
DeGette	Kilpatrick	Peterson (MN)
DeLauro	Kind (WI)	Pickett
Deutsch	Kleczka	Poshard
Doggett	Klink	Price (NC)
Dooley	Kucinich	Rahall
Doyle	LaFalce	Reyes
Edwards	Rivers	Sherman
Rodriguez	Sisisky	Tierney
Roemer	Skaggs	Torres
Rothman	Skelton	Towns
Roukema	Slaughter	Turner
Roybal-Allard	Snyder	Velazquez
Rush	Spratt	Vento
Salmon	Stark	Visclosky
Sanchez	Stenholm	Wamp
Sanders	Strickland	Waters
Sandlin	Stupak	Watt (NC)
Scarborough	Tanner	Waxman
Schumer	Tauscher	Wexler
Scott	Taylor (MS)	Weygand
Serrano	Thompson	Wise
Shays	Thurman	Woolsey

NOT VOTING—17

Barton	Gonzalez	Murtha
Burton	Goodling	Riley
Cubin	Klug	Schiff
Dingell	Martinez	Smith (OR)
Flake	McCrery	Yates
Foglietta	McDermott	

So the resolution was agreed to.

A motion to reconsider the vote whereby said resolution was agreed to was, by unanimous consent, laid on the table.

Pursuant to section 6 of House Resolution 311, H. Res. 306 was laid on the table.

¶130.57 APPOINTMENT OF COMMITTEE TO NOTIFY THE PRESIDENT

Pursuant to House Resolution 311, the following resolution (H. Res. 320) was considered as agreed to:

Resolved, That a committee of two Members of the House be appointed to wait upon the President of the United States and inform him that the House of Representatives has completed its business of the session and is ready to adjourn, unless the President has some other communication to make to them.

¶130.58 JOINT SESSION TO RECEIVE THE PRESIDENT'S MESSAGE

Pursuant to House Resolution 311, the following concurrent resolution (H. Con. Res. 194) was considered as agreed to:

Resolved by the House of Representatives (the Senate concurring), That the two Houses of Congress assemble in the Hall of the House of Representatives on Tuesday, January 27, 1998, at 9 p.m. for the purpose of receiving such communication as the President of the United States shall be pleased to make to them.

¶130.59 ORDER OF BUSINESS—SUSPENSION OF THE RULES

On motion of Mr. ARMEY, by unanimous consent,

Ordered, That the Speaker be authorized to designate a time not later than November 14, 1997, for resumption of proceedings on the seven remaining motions to suspend the rules originally considered on Monday, September 29, 1997.

¶130.60 ADJOURNMENT OVER

On motion of Mr. ARMEY, by unanimous consent,

Ordered, That when the House adjourns today, it adjourn to meet on Wednesday, November 12, 1997 at 12 o'clock noon.

¶130.61 CALENDAR WEDNESDAY BUSINESS DISPENSED WITH

On motion of Mr. ARMEY, by unanimous consent,

Ordered, That business in order for consideration on Wednesday, November 12, 1997, under clause 7, rule XXIV, the Calendar Wednesday rule, be dispensed with.

¶130.62 FURTHER CONTINUING APPROPRIATIONS, FY 1998

On motion of Mr. ARMEY, by unanimous consent, the Committee on House Oversight was discharged from further consideration of the joint resolution (H.J. Res. 103) waiving certain enrollment requirements with respect to certain specified bills of the One Hundred Fifth Congress; the joint resolution was considered and passed.

A motion to reconsider the vote whereby the joint resolution was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said joint resolution.

¶130.63 FURTHER CONTINUING APPROPRIATIONS, FY 1998

On motion of Mr. LIVINGSTON, by unanimous consent, the Committee on Appropriations was discharged from further consideration of the joint resolution (H.J. Res. 105) making further continuing appropriations for the fiscal year 1998, and for other purposes.

When said joint resolution was considered, read twice, ordered to be engrossed and read a third time, was read a third time by title, and passed.

A motion to reconsider the vote whereby the joint resolution was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said joint resolution.

¶130.64 NATIONAL ACADEMY OF SCIENCES AND THE NATIONAL ACADEMY OF PUBLIC ADMINISTRATION

Mr. HORN moved to suspend the rules and pass the bill (H.R. 2977) to amend the Federal Advisory Committee Act to clarify public disclosure requirements that are applicable to the National Academy of Sciences and the National Academy of Public Administration.

The SPEAKER pro tempore, Mr. PEASE, recognized Mr. HORN and Mr. WAXMAN, each for 20 minutes.

After debate,

The question being put, viva voce,

Will the House suspend the rules and pass said bill?

The SPEAKER pro tempore, Mr. PEASE, announced that two-thirds of the Members present had voted in the affirmative.

So, two-thirds of the Members present having voted in favor thereof, the rules were suspended and said bill was passed.

A motion to reconsider the vote whereby the rules were suspended and said bill was passed was, by unanimous consent, laid on the table.

Ordered, That the Clerk request the concurrence of the Senate in said bill.

¶130.65 ORDER OF BUSINESS—CONSIDERATION OF AMENDMENT—H. RES. 314

On motion of Mr. SOLOMON, by unanimous consent,

Ordered, That upon consideration of the resolution (H. Res. 314) waiving a requirement of clause 4(b) of clause of rule XI with respect to consideration of certain resolution reported from the Committee on Rules, and for other purposes, the following amendment be considered as agreed to:

Page 1, line 5, strike ''November 11'' and insert in lieu thereof ''November 15''.

Page 2, after line 13, insert the following:

(4) The bill (S. 1454) to provide a 6-month extension of highway, highway safety and transit programs pending enactment of a law reauthorizing the Intermodal Surface Transportation Efficiency Act of 1991.

Page 2, line 14, strike ''November 11'' and insert in lieu thereof ''November 15''.

¶130.66 SENATE BILLS AND CONCURRENT RESOLUTIONS REFERRED

Bills and a concurrent resolution of the Senate of the following titles were taken from the Speaker's table and, under the rule, referred as follows:

S. 508. An Act to provide for the relief of Mai Hoa ''Jasmin'' Salehi; to the Committee on the Judiciary.

S. 759. An Act to amend the State Department Basic Authorities Act of 1956 to require the Secretary of State to submit an annual report to Congress concerning diplomatic immunity; to the Committee on International Relations.

S. 857. An Act for the relief of Roma Salobrit; to the Committee on the Judiciary.

S. 1189. An Act to increase the criminal penalties for assaulting or threatening Federal judges, their family members, and other public servants, and for other purposes; to the Committee on the Judiciary.

S. 1304. An Act for the relief of Belinda McGregor; to the Committee on the Judiciary.

S. 1487. An Act to establish a National Voluntary Mutual Reunion Registry; to the Committee on Ways and Means.

S. 1507. An Act to amend the National Defense Authorization Act for Fiscal Year 1998 to make certain technical corrections; to the Committee on National Security.

S. Con. Res. 58. Concurrent resolution expressing the concern of Congress over Russia's newly passed religion law; to the Committee on International Relations.

¶130.67 ENROLLED BILLS AND JOINT RESOLUTION SIGNED

Mr. THOMAS, from the Committee on House Oversight, reported that that committee had examined and found truly enrolled bills and a joint resolution of the House of the following titles, which were thereupon signed by the Speaker:

H.R. 1747. An Act to amend the John F. Kennedy Center Act to authorize the design and construction of additions to the parking garage and certain site improvements, and for other purposes.

H.R. 1787. An Act to assist in the conservation of Asian elephants by supporting and providing financial resources for the conservation programs of nations within the range of Asian elephants and projects with demonstrated expertise in the conservation of Asian elephants.

H.R. 2731. An Act for the relief of Roy Desmond Moser.

H.R. 2732. An Act for the relief of John Andre Chalot.

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

¶130.68 SENATE ENROLLED BILLS SIGNED

The SPEAKER announced his signature to enrolled bills of the Senate of the following titles:

S. 813. An Act to amend chapter 91 of title 18, United States Code, to provide criminal penalties for theft and willful vandalism at national cemeteries.

S. 1377. An Act to amend the act incorporating the American Legion to make a technical correction.

¶130.69 BILL AND JOINT RESOLUTION PRESENTED TO THE PRESIDENT

Mr. THOMAS, from the Committee on House Oversight reported that that committee did on the following dates present to the President, for his approval, a bill and a joint resolution of the House of the following titles:

On November 8, 1997:

H.R. 2264. An Act making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 1998, and for other purposes.

On November 9, 1997:

H.J. Res. 104. Joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes.

¶130.70 LEAVE OF ABSENCE

By unanimous consent, leave of absence was granted—

To Mr. YATES, after 12:30 p.m. on November 8 and for November 9; and

To Mr. UNDERWOOD, for today and the balance of the week.

And then,

¶130.71 ADJOURNMENT

On motion of Mr. SOLOMON, pursuant to the special order heretofore agreed to, at 2 o'clock and 2 minutes a.m., Monday, November 10 (legislative day of November 9), 1997 the House adjourned.

¶130.72 REPORTS OF COMMITTEES ON PUBLIC BILLS AND RESOLUTIONS

Under clause 2 of rule XIII, reports of committees were delivered to the Clerk for printing and reference to the proper calendar, as follows:

Mr. BLILEY: Committee of Conference. Conference report on S. 830. An act to amend the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act to improve the regulation of food, drugs, devices, and biological products, and for other purposes (Rept. No. 105–399). Ordered to be printed.

Mr. DIAZ-BALART: Committee on Rules. House Resolution 319. Resolution providing for consideration of the bill (S. 738) to reform the statutes relating to Amtrak, and for other purposes (Rept. No. 105–400). Referred to the House Calendar.

¶130.73 PUBLIC BILLS AND RESOLUTIONS

Under clause 5 of Rule X and clause 4 of Rule XXII, public bills and resolutions were introduced and severally referred, as follows:

By Mr. HORN (for himself, Mrs. MALONEY of New York, Mr. BURTON of Indiana, and Mr. WAXMAN):

H.R. 2977. A bill to amend the Federal Advisory Committee Act to clarify public disclosure requirements that are applicable to the National Academy of Sciences and the National Academy of Public Administration; to the Committee on Government Reform and Oversight.

By Ms. VELAZQUEZ (for herself, Mr. GUTIERREZ, and Mr. SERRANO):

H.R. 2978. A bill to require the Secretary of the Treasury to mint coins in commemoration of all the brave and gallant Puerto Ricans in the 65th Infantry Regiment of the United States Army who fought in the Korean conflict; to the Committee on Banking and Financial Services.

By Mr. THOMAS:

H.R. 2979. A bill to authorize acquisition of certain real property for the Library of Congress, and for other purposes; to the Committee on House Oversight.

By Mr. ALLEN:

H.R. 2980. A bill to amend the Solid Waste Disposal Act to require a refund value for certain beverage containers, to provide resources for State pollution prevention and recycling programs, and for other purposes; to the Committee on Commerce.

By Mr. ALLEN (for himself and Mr. BALDACCI):

H.R. 2981. A bill to amend the Higher Education Act of 1965 relating to financial responsibility for refunds and during provisional certification and change of ownership; to the Committee on Education and the Workforce.

By Mr. GILMAN:

H.R. 2982. A bill to improve the quality of child care provided through Federal facilities and programs, and for other purposes; to the Committee on Government Reform and Oversight, and in addition to the Committees on House Oversight, and the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SHERMAN (for himself, Mr. FOX of Pennsylvania, Mr. PALLONE, Mr. VISCLOSKY, Mr. BONIOR, Ms. ESHOO, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Mr. ROGAN, Mr. WEYGAND, Mr. RADANOVICH, Mr. MORAN of Virginia, Mr. KENNEDY of Massachusetts, and Mr. MARKEY):

H.R. 2983. A bill to promote long term stability in the Caucasus, deter renewed aggression, and facilitate the peaceful resolution of the Nagorno-Karabagh conflict; to the Committee on International Relations, and in addition to the Committee on Banking and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. BARR of Georgia:

H.R. 2984. A bill to provide an exemption from the Gun-Free School Zones Act of 1990 for conduct that does not violate State or local law; to the Committee on the Judiciary.

By Mr. CARDIN (for himself, Mr. BUNNING of Kentucky, Mr. ENGLISH of Pennsylvania, Mr. ENSIGN, Mr. STARK, and Mr. WELLER):

H.R. 2985. A bill to amend the Immigration and Nationality Act to make certain aliens determined to be delinquent in the payment of child support inadmissible, deportable, and ineligible for naturalization, to authorize immigration officers to serve process in child support cases on aliens entering the United States, and for other purposes; to the Committee on the Judiciary, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of

such provisions as fall within the jurisdiction of the committee concerned.

By Mr. COLLINS:

H.R. 2986. A bill for the relief of the survivors of the 14 members of the Armed Forces and the one United States civilian who were killed on April 14, 1994, when United States fighter aircraft mistakenly shot down 2 helicopters in Iraq; to the Committee on the Judiciary.

By Mr. DAVIS of Virginia (for himself and Mr. KUCINICH):

H.R. 2987. A bill to amend title 5, United States Code, to provide for appropriate overtime pay for National Weather Service forecasters performing essential services during severe weather events, and for other purposes; to the Committee on Government Reform and Oversight.

By Mr. DOOLITTLE:

H.R. 2988. A bill to facilitate the operation, maintenance, and upgrade of certain federally owned hydroelectric power generating facilities, to ensure the recovery of costs, and to improve the ability of the Federal Government to coordinate its generating and marketing of electricity with the non-Federalelectric utility industry; to the Committee on Resources, and in addition to the Committees on Commerce, and Transportation and Infrastructure, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. ENSIGN:

H.R. 2989. A bill to direct the Secretary of the Interior to convey to the St. Jude's Ranch for Children, Nevada, approximately 40 acres of land in Las Vegas, Nevada, to be used for the development of facilities for the residential care and treatment of adjudicated girls; to the Committee on Resources.

By Mr. ENSIGN (for himself, Mr. RANGEL, Mr. LAZIO of New York, Mr. CHRISTENSEN, Mr. GIBBONS, Ms. LOFGREN, Mr. ENGLISH of Pennsylvania, Mr. BACHUS, Mr. RILEY, Mr. CALLAHAN, Mr. KENNEDY of Massachusetts, Mr. MICA, Mr. EVERETT, Mr. THOMPSON, Mr. HOUGHTON, Mr. WEYGAND, Mr. ADERHOLT, Mr. CARDIN, Mr. HILLIARD, Mr. CRAMER, Ms. DANNER, Ms. PELOSI, Mr. SKELTON, Mr. DIAZ-BALART, Mr. FILNER, Mr. FROST, Mr. CRAPO, Mr. ADAM SMITH of Washington, Mr. REYES, Mr. NEAL of Massachusetts, Ms. WOOLSEY, and Mr. KUCINICH):

H.R. 2990. A bill to amend the Internal Revenue Code of 1986 to increase the amount of low-income housing credits which may be allocated in each State, and to index such amount for inflation; to the Committee on Ways and Means.

By Ms. ESHOO (for herself and Mr. TAUZIN):

H.R. 2991. A bill to enhance electronic commerce by requiring agencies to use digital signatures, which are compatible with standards for such technology used in commerce and industry, to enable persons to submit Federal forms electronically, and for other purposes; to the Committee on Government Reform and Oversight, and in addition to the Committee on Commerce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. GRAHAM (for himself, Mr. SAM JOHNSON, Mr. HILLEARY, Mr. INGLIS of South Carolina, Mr. WAMP, Mr. NORWOOD, Mr. BARTLETT of Maryland, Mr. TAYLOR of North Carolina, Mr. STUMP, Mr. HERGER, Mr. MILLER of Florida, Mr. WATTS of Oklahoma, Mr. ISTOOK, Mrs. LINDA SMITH of Washington, Mr. TALENT, Mr. THORNBERRY, Mr. CHABOT, Mr. SPENCE, Mr. SANFORD, Mr. TIAHRT, Mr. KNOLLENBERG, Mrs. MYRICK, Mr. HEFLEY, Mr. SOLOMON, Mr. BARTON of Texas, Mr. PITTS, Ms. DUNN of Washington, Mr. SALMON, Mr. SHADEGG, Mr. LARGENT, Mr. BACHUS, Mr. BALLENGER, Mr. DICKEY, Mr. BLUNT, Mrs. EMERSON, Mr. LAHOOD, Mr. MCKEON, Mr. RADANOVICH, Mr. ROHRABACHER, Mr. COX of California, Mr. SENSENBRENNER, Mr. HUTCHINSON, Mr. HOSTETTLER, Mr. BOB SCHAFFER, Mr. PETERSON of Pennsylvania, Mr. SOUDER, Mr. MCINTOSH, Mr. SESSIONS, Mr. ROYCE, Mr. WELDON of Florida, and Mr. NETHERCUTT):

H.R. 2992. A bill to repeal the Goals 2000: Educate America Act and the National Skill Standards Act of 1994 to allow local areas to develop elementary and secondary education programs that meet their needs; to the Committee on Education and the Workforce.

By Mr. HEFLEY:

H.R. 2993. A bill to provide for the collection of fees for the making of motion pictures, television productions, and sound tracks in National Park System and National Wildlife Refuge System units, and for other purposes; to the Committee on Resources.

By Ms. HOOLEY of Oregon (for herself and Mr. DAVIS of Virginia):

H.R. 2994. A bill to provide for various capital investments in technology education in the United States; to the Committee on Education and the Workforce, and in addition to the Committees on Science, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. JOHNSON of Connecticut (for herself and Mrs. LOWEY):

H.R. 2995. A bill to amend the Internal Revenue Code of 1986 to allow tax-exempt organizations (other than governmental units) a credit against employment taxes in an amount equivalent to the work opportunity credit allowable to taxable employers, and for other purposes; to the Committee on Ways and Means.

By Mr. KENNEDY of Massachusetts:

H.R. 2996. A bill to amend the Securities Exchange Act of 1934 to revise the definition of limited partnership rollup transaction; to the Committee on Commerce.

By Mr. KENNEDY of Massachusetts (for himself, Mr. DELLUMS, Mr. KLECZKA, Mr. LAFALCE, Mr. FILNER, Mr. MCDERMOTT, Mr. BONIOR, Mr. TOWNS, Ms. SLAUGHTER, Mr. LEWIS of Georgia, Mr. JACKSON, Ms. VELAZQUEZ, Mr. MCGOVERN, Mr. BERMAN, Ms. PELOSI, Mr. OLVER, Mr. MARKEY, Mr. WAXMAN, Ms. NORTON, Ms. KILPATRICK, Mr. MEEHAN, Ms. ROYBAL-ALLARD, Mr. MILLER of California, Mrs. MALONEY of New York, Mr. GUTIERREZ, Mr. DELAHUNT, Ms. CARSON, Mr. MARTINEZ, Mrs. MEEK of Florida, Mr. HINCHEY, Mr. OWENS, Mr. TIERNEY, Mr. FATTAH, Mr. PAYNE, Mr. NEAL of Massachusetts, Mr. ACKERMAN, Ms. WATERS, Ms. BROWN of Florida, Mr. POMEROY, and Ms. HOOLEY of Oregon):

H.R. 2997. A bill to establish a commission on fairness in the workplace; to the Committee on Education and the Workforce.

By Mr. LEVIN (for himself and Mr. KILDEE):

H.R. 2998. A bill to amend the Internal Revenue Code of 1986 to exclude from gross income certain amounts received as scholarships by an individual under the National Health Service Corps Scholarship Program; to the Committee on Ways and Means.

By Mr. LEVIN:

H.R. 2999. A bill to amend title XVIII and XIX of the Social Security Act to expand and clarify the requirements regarding advance directives in order to ensure that an individual's health care decisions are complied with, and for other purposes; to the Committee on Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. OXLEY (for himself, Mr. CONDIT, Mr. JOHN, Mr. BLILEY, Mr. FORD, Mr. UPTON, Mr. GREENWOOD, Mr. KLUG, Mr. MARTINEZ, Mr. GOODLING, Mr. TRAFICANT, Mr. TAUZIN, Mr. PETERSON of Minnesota, Mr. Dan SCHAEFER of Colorado, Mr. STENHOLM, Mr. GILLMOR, Mr. BISHOP, Mr. PAXON, Mr. SISISKY, Mr. LARGENT, Mr. BAESLER, Mr. BUYER, Mr. GOODE, Mr. FRELINGHUYSEN, Mr. BOYD, Mrs. EMERSON, Mr. CRAMER, Mr. BARRETT of Nebraska, Mr. HOLDEN, Mr. BURR of North Carolina, Mr. PICKETT, Mr. HEFLEY, Mr. MCINTYRE, Mr. DUNCAN, Mr. SANDLIN, Mr. PETERSON of Pennsylvania, and Mr. RUSH):

H.R. 3000. A bill to amend the Comprehensive Environmental, Response, Compensation, and Liability Act of 1980; to the Committee on Commerce, and in addition to the Committees on Transportation and Infrastructure, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. LOWEY (for herself, Mrs. JOHNSON of Connecticut, Mr. HOYER, Mrs. MORELLA, Mr. NADLER, Mr. STEARNS, Ms. DELAURO, Mr. LEACH, Mr. LEWIS of Georgia, Mr. WICKER, and Mr. CARDIN):

H.R. 3001. A bill to amend the Public Health Service Act to provide additional support for and to expand clinical research programs, and for other purposes; to the Committee on Commerce.

By Mrs. LOWEY:

H.R. 3002. A bill to expand the educational and work opportunities of welfare recipients under the program of block grants to States for temporary assistance for needy families; to the Committee on Ways and Means.

By Mr. MCCOLLUM (for himself, Mr. LEACH, Mr. LAFALCE, Mrs. ROUKEMA, Mr. BEREUTER, Mr. BAKER, Mr. BACHUS, Mr. KING of New York, Mr. ROYCE, Mr. EHRLICH, Mr. BARR of Georgia, Mr. COOK, Mr. SESSIONS, Mr. HILL, and Mr. BONO):

H.R. 3003. A bill to amend the Federal Deposit Insurance Act and the Federal Credit Union Act to safeguard confidential banking and credit union information, and for other purposes; to the Committee on Banking and Financial Services.

By Mrs. MALONEY of New York (for herself, Mrs. MORELLA, and Mr. COBURN):

H.R. 3004. A bill to amend part E of title IV of the Social Security Act to require States to administer qualifying examinations to all State employees with new authority to make decisions regarding child welfare services, to expedite the permanent placement of foster children, to facilitate the placement of foster children in permanent kinship care arrangements, and to require State agencies, in considering applications to adopt certain foster children, to give preference to applications of a foster parent or caretaker relative of the child; to the Committee on Ways and Means.

By Mrs. MALONEY of New York (for herself, Mr. DELLUMS, Mr. MANTON, and Mr. PETERSON of Minnesota):

H.R. 3005. A bill to amend part E of title IV of the Social Security Act to require States to have laws that would permit a parent who is chronically ill or near death to name a standby guardian for a minor child without surrendering parental rights; to the Committee on Ways and Means.

By Ms. MILLENDER-MCDONALD:

H.R. 3006. A bill to direct the Attorney General to provide a written opinion regarding the constitutionality of proposed state ballot initiatives, and for other purposes; to the Committee on the Judiciary.

By Mrs. MORELLA:

H.R. 3007. A bill to establish the Commission on the Advancement of Women in Science, Engineering, and Technology Development; to the Committee on Education and the Workforce, and in addition to the Committee on Science, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. NEUMANN:

H.R. 3008. A bill to amend title II of the Social Security Act to allow workers who attain age 65 after 1981 and before 1992 to choose either lump sum payments over four years totalling $5,000 or an improved benefit computation formula under a new 10-year rule governing the transition to the changes in benefit computation rules enacted in the Social Security Amendments of 1977, and for other purposes; to the Committee on Ways and Means, and in addition to the Committee on the Budget, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PALLONE (for himself, Mr. GILMAN, Mr. BROWN of Ohio, Mr. FOX of Pennsylvania, Ms. SANCHEZ, Mr. HORN, Ms. ESHOO, Mr. GREEN, Mr. FROST, Mr. ANDREWS, Mr. FILNER, Mr. ACKERMAN, Mr. WEXLER, Mr. BROWN of California, Mrs. MALONEY of New York, Mr. HASTINGS of Florida, Mr. PASCRELL, Mr. MASCARA, Mr. DAVIS of Illinois, Ms. MILLENDER-MCDONALD, Ms. CARSON, Mrs. CLAYTON, Mr. LAMPSON, Mr. NADLER, Ms. JACKSON-LEE, Mr. ROTHMAN, Mr. ENGEL, Mr. PAYNE, Mr. MCCOLLUM, Mr. SHERMAN, Mr. CRAMER, and Mrs. MORELLA):

H.R. 3009. A bill to amend the Public Health Service Act and the Employee Retirement Income Security Act of 1974 to establish standards for managed care plans; to the Committee on Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PALLONE (for himself, Mr. SHERMAN, Mr. FOX of Pennsylvania, Mr. VISCLOSKY, Mr. BONIOR, Ms. ESHOO, Mr. KENNEDY of Rhode Island, Mr. ROTHMAN, Mr. ROGAN, Mr. WEYGAND, Mr. RADANOVICH, Mr. MARKEY, Mr. MORAN of Virginia, and Mr. KENNEDY of Massachusetts):

H.R. 3010. A bill to amend the Foreign Assistance Act of 1961 to target assistance to support the economic and political independence of the countries of the South Caucasus; to the Committee on International Relations, and in addition to the Committees on Ways and Means, and Banking and Financial Services, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. PASCRELL:

H.R. 3011. A bill to amend the Internal Revenue Code of 1986 to exclude certain severance payment amounts from income; to the Committee on Ways and Means.

By Mr. POMEROY:

H.R. 3012. A bill to amend Public Law 89–108 to increase authorization levels for State and Indian tribal, municipal, rural, and industrial water supplies, to meet current and future water quantity and quality needs of the Red River Valley, to deauthorize certain project features and irrigation service areas, to enhance natural resources and fish and wildlife habitat, and for other purposes; to the Committee on Resources.

By Ms. PRYCE of Ohio (for herself, Mr. EWING, and Mr. GREENWOOD):

H.R. 3013. A bill to reduce the incidence of child abuse and neglect, and for other purposes; to the Committee on the Judiciary.

By Mr. RADANOVICH (for himself, Mr. BILBRAY, Ms. ESHOO, Mr. MILLER of California, Mr. ROGAN, Mr. LEWIS of California, Ms. PELOSI, Mr. POMBO, and Mr. FARR of California):

H.R. 3014. A bill to amend the Consolidated Omnibus Budget Reconciliation Act of 1985 to expand the number of county operated health insuring organizations authorized to enroll Medicaid beneficiaries; to the Committee on Commerce.

By Mr. SANDERS:

H.R. 3015. A bill to provide additional appropriations for certain nutrition programs; to the Committee on Appropriations.

By Mr. SANDERS (for himself, Mr. SHAYS, and Mr. DEFAZIO):

H.R. 3016. A bill to amend section 332 of the Communications Act of 1934 to preserve State and local authority to regulate the placement, construction, and modification of certain telecommunications facilities, and for other purposes; to the Committee on Commerce.

By Mr. SANDERS:

H.R. 3017. A bill calling for ratification of the United Nations Convention on the Rights of the Child; to the Committee on International Relations, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. SCARBOROUGH (for himself and Mrs. THURMAN):

H.R. 3018. A bill to release the reversionary interests retained by the United States in four deeds that conveyed certain lands to the State of Florida so as to permit the State to sell, exchange, or otherwise dispose of the lands, and to provide for the conveyance of certain mineral interests of the United States in the lands to the State of Florida; to the Committee on Agriculture, and in addition to the Committee on Resources, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mrs. LINDA SMITH of Washington:

H.R. 3019. A bill to amend the Federal Election Campaign Act of 1971 to prohibit the use of soft money by political parties, to permit individuals to elect to not have payroll deductions used for political activities, and for other purposes; to the Committee on House Oversight, and in addition to the Committee on the Judiciary, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. STOKES:

H.R. 3020. A bill to establish a program, primarily through the States and municipalities, and their agents, to facilitate the environmental assessment, cleanup, and reuse of abandoned or underutilized, potentially contaminated properties not on, or proposed for inclusion on, the National Priorities List; to the Committee on Commerce, and in addition to the Committees on Transportation and Infrastructure, and Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. STUPAK:

H.R. 3021. A bill to amend the Omnibus Crime Control and Safe Streets Act of 1968 to reduce certain funds if eligible States do not enact certain laws; to the Committee on the Judiciary.

By Mr. WATT of North Carolina (for himself, Mr. CONYERS, and Mr. COLLINS):

H.R. 3022. A bill to amend title 10, United States Code, to authorize the settlement and payment of claims against the United States for injury and death of members of the Armed Forces and Department of Defense civilian employees arising from incidents in which claims are settled for death or injury of foreign nationals; to the Committee on the Judiciary.

By Mr. WELDON of Pennsylvania (for himself and Mr. MARKEY):

H.R. 3023. A bill to end American subsidization of entities contributing to weapons proliferation; to the Committee on Intelligence (Permanent Select), and in addition to the Committees on Banking and Financial Services, and International Relations, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. LIVINGSTON:

H.J. Res. 104. A joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes; to the Committee on Appropriations. November 9, 1997, The Committee on Appropriations discharged, considered and passed.

By Mr. LIVINGSTON:

H.J. Res. 105. A joint resolution making further continuing appropriations for the fiscal year 1998, and for other purposes; to the Committee on Appropriations: November 10 (Legislative Day, November 9), 1997, the Committee on Appropriations discharged; considered and passed.

By Ms. VELAZQUEZ (for herself, Mr. GUTIERREZ, and Mr. SERRANO):

H. Con. Res. 192. Concurrent resolution expressing the sense of the Congress that the heroism of the brave and gallant Puerto Ricans in the 65th Infantry Regiment of the United States Army who fought in the Korean conflict should be commemorated; to the Committee on Veterans' Affairs, and in addition to the Committee on National Security, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned.

By Mr. MICA (for himself, Mr. CONDIT, Mr. UPTON, Mr. WELDON of Florida, Mr. NORWOOD, Mr. PAPPAS, Mrs. FOWLER, Mr. SCARBOROUGH, Mr. SALMON, Mr. PITTS, Mr. HILLEARY, Mr. ROHRABACHER, Mr. CUNNINGHAM, Mr. DOOLITTLE, Mr. MILLER of Florida, Mr. HERGER, Mr. STEARNS, Mr. POMBO, Mr. LUCAS of Oklahoma, Mr. KINGSTON, Mr. SANFORD, Mr. JONES, Mr. BRADY, Mr. BACHUS, Mr. ROGAN, Mr. PICKERING, Mr. LAZIO of New York, Mr. INGLIS of South Carolina, Mr. PORTMAN, Mr. BLUNT, Mr. SHIMKUS, Mr. HEFLEY, Mr. HOSTETTLER, Mr. BURTON of Indiana, Mr. CHAMBLISS, Mr. LATOURETTE, Mr. WELLER, Mr. YOUNG of Florida, Mr.

MCDADE, Mr. CALLAHAN, Mr. FOLEY, Mr. FOSSELLA, Mr. DICKEY, Mr. WAMP, Mr. COX of California, Mr. MANZULLO, Mr. GILCHREST, Mr. BARTLETT of Maryland, Mr. RIGGS, Mr. SAXTON, Mr. SHAYS, Mr. THOMAS, Mr. PAUL, Mr. HAYWORTH, Mr. BUYER, Mr. WICKER, Mrs. KELLY, Mr. COLLINS, Mr. EVERETT, Mr. LOBIONDO, Mr. HORN, Mr. KNOLLENBERG, Mr. RAMSTAD, Mr. MORAN of Virginia, Mr. ENSIGN, Mr. NETHERCUTT, Mrs. LINDA SMITH of Washington, Mr. RYUN, Mr. FRANKS of New Jersey, Mrs. CHENOWETH, Mr. SOUDER, Mr. TIAHRT, Mr. GUTKNECHT, Mr. KLUG, Mr. MCCOLLUM, Mr. MCKEON, Mr. DUNCAN, Mr. ENGLISH of Pennsylvania, Mr. THUNE, Mr. SMITH of New Jersey, Ms. GRANGER, Mr. SMITH of Michigan, Mr. WATKINS, Mr. BURR of North Carolina, Mr. WATTS of Oklahoma, Mr. STENHOLM, Mr. PETERSON of Minnesota, Mr. BOYD, Mr. OBERSTAR, Mr. CRANE, and Mr. EHLERS):

H. Con. Res. 193. Concurrent resolution expressing the sense of the Congress that the Attorney General should remove Hani El-Sayegh from the United States to the Kingdom of Saudi Arabia; to the Committee on the Judiciary.

By Mr. SOLOMON:

H. Con. Res. 194. Concurrent resolution providing for a joint session of Congress to receive a message from the President; adopted pursuant to H. Res. 311.

By Ms. HARMAN (for herself, Mr. SAWYER, Mr. REGULA, Mr. SPRATT, Mr. DAVIS of Virginia, Mr. PORTMAN, Mr. BECERRA, Mr. HASTINGS of Florida, Mr. BARRETT of Wisconsin, Mr. WATT of North Carolina, Ms. ROS-LEHTINEN, Mr. HOUGHTON, Mr. DICKEY, Mr. LEWIS of Georgia, Mr. MATSUI, and Ms. MILLENDER-MCDONALD):

H. Con. Res. 195. Concurrent resolution expressing the sense of Congress in support of National Days of Dialogue associated with the national celebration of the birth of Dr. Martin Luther King, Jr. to improve understanding and cooperation across race, ethnicity, culture, gender, religion and creed; to the Committee on the Judiciary.

By Mr. DAN SCHAEFER of Colorado:

H. Res. 317. A resolution providing for the agreement of the House to the Senate amendment to the bill, H.R. 2472, with an amendment; considered and agreed to.

By Mr. GEPHARDT:

H. Res. 318. Resolution relating to a question of the privileges of the House; considered and laid on the table.

By Mr. SOLOMON:

H. Res. 320. Resolution providing for a committee to notify the President of completion of business; adopted pursuant to H. Res. 311.

By Mr. KENNEDY of Massachusetts:

H. Res. 321. A resolution expressing the sense of the House of Representatives that college and university administrators should adopt a code of principles to change the culture of alcohol consumption on college campuses; to the Committee on Education and the Workforce.

¶130.74 MEMORIALS

Under clause 4 of rule XXII, memorials were presented and referred as follows:

225. The SPEAKER presented a memorial of the House of Representatives of the Commonwealth of Pennsylvania, relative to House Resolution No. 295 memorializing the Citizens' Committee of the United States Postal Service to consider and recommend to the United States Postal Service Board of Governors the issuance of a commemorative stamp honoring Richard Humphreys, Quaker, goldsmith and philanthropist, on the 160th Anniversary of the founding of Cheyney University of Pennsylvania; to the Committee on Government Reform and Oversight.

226. Also, a memorial of the Legislature of the State of California, relative to Assembly Joint Resolution 38 expressing support for a full, fair, and complete investigation of legal and ethical violations during the 1996 campaigns, and memorializing the President and the Congress to condemn all prejudice against Asian and Pacific Islander Americans, and to publicly support political and civic participation by these persons throughout the United States; to the Committee on the Judiciary.

227. Also, a memorial of the Legislature of the State of California, relative to Assembly Joint Resolution 32 memorializing the President and Congress of the United States to recognize the sacrifices and services rendered to our country by the Hmong-Lao veterans who served in the special guerrilla units that were allied with, and operating in support of, the military forces of the United States during the Vietnam War by granting those veterans and their families full United States citizenship; to the Committee on the Judiciary.

¶130.75 ADDITIONAL SPONSORS

Under clause 4 of rule XXII, sponsors were added to public bills and resolutions as follows:

H.R. 27: Mr. RIGGS.
H.R. 34: Mr. SUNUNU.
H.R. 225: Mr. ABERCROMBIE.
H.R. 251: Mr. PETERSON of Pennsylvania.
H.R. 352: Mr. SALMON.
H.R. 409: Mr. PAPPAS.
H.R. 530: Mr. BEREUTER and Mr. CALVERT.
H.R. 543: Mr. SOLOMON, Mr. NETHERCUTT, Mr. DIXON, and Mr. HYDE.
H.R. 586: Mr. JOHNSON of Wisconsin.
H.R. 738: Ms. SLAUGHTER.
H.R. 820: Ms. FURSE.
H.R. 979: Mr. JOHNSON of Wisconsin and Ms. WATERS.
H.R. 992: Mr. DEAL of Georgia and Mr. HUTCHINSON.
H.R. 1151: Mr. ABERCROMBIE and Mr. SESSIONS.
H.R. 1289: Mr. YATES.
H.R. 1334: Mr. RIGGS and Ms. PELOSI.
H.R. 1415: Mr. GOODLING.
H.R. 1519: Mr. STOKES.
H.R. 1525: Mr. MCNULTY.
H.R. 1591: Mr. BARR of Georgia, Mr. SNOWBARGER, and Mr. SCARBOROUGH.
H.R. 1628: Mr. KIM.
H.R. 1635: Mr. BAESLER, Mr. SAXTON, Mr. LEACH, Mr. COSTELLO, Mrs. LOWEY, Mr. HINCHEY, Mr. ROMERO-BARCELO, Mr. HORN, Mr. WAXMAN, and Mr. SKAGGS.
H.R. 1822: Mr. JOHNSON of Wisconsin.
H.R. 1872: Mr. GREENWOOD, Mr. STRICKLAND, Mr. DAVIS of Virginia, Mr. PALLONE, Mr. LINDER, Mr. DICKS, Mr. GREEN, and Mr. RUSH.
H.R. 1891: Mr. BOEHNER.
H.R. 2053: Mr. LOFGREN.
H.R. 2131: Mr. JOHNSON of Wisconsin.
H.R. 2174: Mr. MALONEY of Connecticut.
H.R. 2229: Mr. WATTS of Oklahoma.
H.R. 2273: Mr. STUPAK, Mr. BAESLER, Mr. MALONEY of Connecticut, and Mr. HUTCHINSON.
H.R. 2319: Mr. LUTHER.
H.R. 2321: Mr. RIGGS.
H.R. 2335: Mr. CONDIT.
H.R. 2363: Mr. CABOT, Mr. DREIER, Mr. KOLBE, Mr. LIVINGSTON, Mr. RYUN, Mr. SAXTON, Mr. SMITH of Oregon, Mr. SOLOMON, Mr. SPENCE, and Mr. WICKER.
H.R. 2369: Mr. CAMPBELL.
H.R. 2391: Mr. KUCINICH, and Mr. MCGOVERN.
H.R. 2397: Ms. SLAUGHTER.
H.R. 2436: Mr. LAFALCE.
H.R. 2483: Mr. FRANKS of New Jersey.
H.R. 2500: Mr. ARMEY, Mr. BAESLER, Mr. BAKER, Mr. BALLENGER, Mr. BARCIA of Michigan, Mr. BARR of Georgia, Mr. BARRETT of Nebraska, Mr. BARTLETT of Maryland, Mr. BARTON of Texas, Mr. BEREUTER, Mr. BLAGOJEVICH, Mr. BLILEY, Mr. BOEHLERT, Mr. BOEHNER, Mr. BONILLA, Mr. BONO, Mr. BOYD, Mr. BRYANT, Mr. BUNNING of Kentucky, Mr. BURR of North Carolina, Mr. CALVERT, Mr. CANADY of Florida, Mr. CHABOT, Mr. CHAMBLISS, Mr. CHRISTENSEN, Mr. CLEMENT, Mr. COBLE, Mr. CONDIT, Mr. COOK, Mr. COOKSEY, Mr. COX of California, Mr. CRANE, Mr. DEAL of Georgia, Mr. DEUTSCH, Mr. DOOLEY of California, Mr. DREIER, Ms. DUNN of Washington, Mr. EHRLICH, Mr. FATTAH, Mr. FOLEY, Mrs. FOWLER, Mr. FOX of Pennsylvania, Mr. FROST, Ms. FURSE, Mr. GILMAN, Mr. GOODE, Mr. GOODLATTE, Mr. GOODLING, Mr. GORDON, Mr. GOSS, Mr. HALL of Texas, Mr. HANSEN, Mr. HASTERT, Mr. HEFLEY, Mr. HILL, Mr. HOLDEN, Mr. HUNTER, Mr. HUTCHINSON, Mr. INGLIS of South Carolina, Mr. JENKINS, Mr. JONES, Mr. SAM JOHNSON, Mr. KASICH, Mrs. KELLY, Mr. KENNEDY of Rhode Island, Mr. KING of New York, Mr. LATOURETTE, Mr. LEWIS of California, Mr. LINDER, Ms. MCCARTHY of Missouri, Mr. MEEHAN, Mr. METCALF, Mr. MORAN of Virginia, Mrs. MYRICK, Mr. NEY, Mrs. NORTHUP, Mr. OXLEY, Mr. PARKER, Mr. PAXON, Mr. PETERSON of Minnesota, Mr. PICKETT, Mr. REDMOND, Mr. RIGGS, Mr. ROEMER, Mr. ROGAN, Mr. ROYCE, Mr. SAXTON, Mr. SCARBOROUGH, Mr. SENSENBRENNER, Mr. SESSIONS, Mr. SHIMKUS, Mr. SISISKY, Mr. SKELTON, Mr. ADAM SMITH of Washington, Mr. SMITH of Texas, Mr. SOLOMON, Mr. SPENCE, Mr. STENHOLM, Mr. TANNER, Mrs. TAUSCHER, Mr. TAUZIN, Mr. WATTS of Oklahoma, Mr. WELDON of Florida, Mr. WELLER, Mr. BURTON of Indiana, Mr. DICKEY, Mr. ARCHER, Mr. QUINN, Mr. LAHOOD, Mr. TIAHRT, Mr. DAVIS of Virginia, Mr. THOMAS, Mr. CUNNINGHAM, Mr. ENSIGN, Mr. GIBBONS, Mr. STUMP, Mr. COMBEST, Mr. HAYWORTH, Mr. ROHRABACHER, Mr. CALLAHAN, Mr. EVERETT, Mr. STEARNS, Mr. DELAY, Mr. GINGRICH, and Mr. LIVINGSTON.
H.R. 2509: Mr. LEWIS of Georgia.
H.R. 2524: Mr. ABERCROMBIE.
H.R. 2593: Mrs. LOWEY, Mr. WAMP, Mr. GRAHAM, Mr. NETHERCUTT, Mr. BRADY, Mr. KNOLLENBERG, Mr. SENSENBRENNER, Mr. MCINTOSH, Mr. HOBSON, Mr. TAYLOR of North Carolina, Mr. WELDON of Pennsylvania, Mr. MICA, Mr. DICKEY, Mr. THOMAS, Mr. CANNON, Mr. SAXTON, Mr. SOLOMON, Mrs. KELLY, Mr. MANZULLO, Mr. WELDON of Florida, Mr. PAXON, Mr. SNOWBARGER, Mr. HORN, Mr. SALMON, Mr. DAN SCHAEFER of Colorado, Mr. NEY, Mr. STUMP, and Mr. RAMSTAD.
H.R. 2611: Mr. BLUNT, Mr. DUNCAN, Mr. TAUZIN, Mr. BARR of Georgia, Mr. BILBRAY, Mr. CANNON, Mr. CHRISTENSEN, Mr. HEFLEY, Mr. MCKEON, Mr. MICA, Mrs. LINDA SMITH of Washington, Mr. SMITH of Oregon, Mr. SOUDER, Mr. SPENCE, Mr. EHRLICH, Mr. RIGGS, and Mr. CRANE.
H.R. 2695: Mr. BONIOR, Mr. DELLUMS, Mr. KUCINICH, Mr. MCGOVERN, Ms. LOFGREN, Mrs. THURMAN, and Ms. MILLENDER-MCDONALD.
H.R. 2750: Mrs. THURMAN.
H.R. 2755: Mr. WAXMAN, Mrs. MINK of HAWAII, Mr. FRANK of MASSACHUSETTS, Mr. FROST, Mr. WALSH, Ms. LOFGREN, Ms. CARSON, Ms. KILPATRICK, Mr. BONIOR, and Mr. EVANS.
H.R. 2760: Mr. CALVERT, Mr. BACHUS, and Mr. RADANOVICH.
H.R. 2780: Mr. CAMPBELL, Mr. LARGENT, Mr. MCINTOSH, Mr. BRYANT, Mr. WHITE, Mr. LATOURETTE, and Mr. SALMON.
H.R. 2819: Mr. HERGER and Ms. HARMAN.
H.R. 2820: Mr. CALVERT.
H.R. 2821: Mr. NEAL of Massachusetts.
H.R. 2826: Ms. SLAUGHTER and Ms. NORTON.